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A RANDOMISED COMPARATIVE STUDY OF I-GEL AND ENDOTRACHEAL TUBE IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY

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Introduction

Surgical procedures involving laparoscopic technique is one of the sub-specialties since the mid-1950, which is not only limited to gynecologic surgery or cholecystectomy but also extended to various other procedures including appendectomy, hernia repairs, and advanced gastrointestinal, and urologic surgical procedures.

A recent study from the United States has reported that approximately 300, 000 cholecystectomies are being performed out of the 20 million people having gallstones annually.(1) However, the prevalence of gallbladder stones in India is 4% compared to 10% in Western Countries.(2)

Laparoscopic cholecystectomy is a minimally invasive surgical procedure that has replaced the open technique for the removal of a diseased gallbladder since the early 1990s. Considering the major benefits of using laparoscopic techniques, these days many major procedures including the anterior resection of rectum or radical cystectomy that require prolonged postoperative recovery are increasingly being performed using laparoscopic techniques to further improve patient outcomes. (3)

However, it also has its specific risks of performing laparoscopic surgery that might be either due to risks associated with individual laparoscopic technique or due to changes in physiologically associated pneumoperitoneum, an integral part of laparoscopy, that could result in respiratory embarrassment and cardiovascular changes can best be managed with the use of general anaesthesia. Considering the associated risk with laparoscopic techniques since the evolution of the application of laparoscopy in various day-care surgeries, refinement in the use of existing anaesthetic techniques is necessary to anticipate these differences. The development of anaesthetic medicine has propelled innovations and initiatives for newer yet safer techniques, besides clinically relevant scales, many fronts have been achieved with the advancements in anaesthesiology.

Despite the requirement of tracheal intubation during administration and maintenance of general anaesthesia in most cases, it is also common that the adverse effects during the procedure could not be ruled out. Among the various adverse effects, hemodynamic perturbations are the major concern to anaesthesiologists during the intraoperative period. Furthermore, it is also reported that high intra-abdominal

pressures generated during surgery due to carbon dioxide insufflation increases the risk of passive gastroesophageal regurgitation and carbon dioxide retention. Due to these reasons, general anaesthesia with controlled ventilation is often achieved with the help of an endotracheal tube (ETT) is one of the most prevalent techniques in terms of safety, while performing laparoscopic cholecystectomy.(4)

It is well known that supraglottic airway devices such as laryngeal mask airway (LMA) or I gel could be the best choice of use instead of tracheal intubation in selected elective cases to minimize the side effects. Compared to the tracheal tubes supraglottic airway devices have several other well-established advantages such as less hemodynamic stress response, lower incidence of sore throat, and increased case turnover.(5)

The use of laryngeal mask airway is in practice since the 1990s and I-gel is one of the new additions in line. Several studies have reported the use of classic LMA or proseal LAM and I-gel in the management of the airway during anaesthesia with positive pressure ventilation. (6)

Release of catecholamines and cortisol were also identified as the causes for an increase in heart rate and pressor response after pharyngeal and laryngotracheal manipulation that are mostly higher after laryngoscopy and tracheal intubation irrespective of the use of any strong opioids. (7)

Even though such responses are of less importance in American Society of Anaesthesiologists (ASA) physical status I patients, they might cause life-threatening conditions in patients with hypertension, ischemic heart disease, diabetes mellitus, and cerebrovascular diseases. Studies have reported that such effects could be decreased with the use of LMA or I-gel during general anaesthesia with mechanical ventilation with adequate oxygenation and ventilation.(8) Several other studies have also shown that either proseal LMA or i-gel could be used safely during positive pressure ventilation with more stable hemodynamics and normal oxygenation and ventilation.(6,9)

Since the development of the supraglottic airway device by a British anesthesiologist Dr. Archie Brain, it is been in clinical use. SADs have been used as a convenient alternative to ETT, with easy and atraumatic insertion, as well as minimal somatic and autonomic responses in many clinical conditions. However, SADs have some

disadvantages, like limited protection of the airway from gastric contents. The second-generation SADs have overcome this issue with the use of the I-Gel, one among the second-generation SDAs, which is made of medical-grade thermoplastic elastomer (styrene ethylene butadiene styrene) and does not require an inflating cuff. Its design provides a peri-laryngeal seal without cuff inflation. In addition, it is easily and rapidly placed, with a reduced risk of pharyngeal tissue compression. Moreover, it has a gastric drainage tube, and it allows the insertion of a gastric tube (maximum 14 Fr) and aspiration of the gastric contents and air. I-gel provides lower respiratory complications and can seal higher oropharyngeal leak pressures than the earlier SADs.

Even though various studies have reported that I-gel is found equally effective device to provide positive pressure ventilation in laparoscopic surgeries with stable hemodynamics, only very few studies with limited data available in the literature to compare I-gel with an endotracheal tube to assess their performance in anesthetized and artificially ventilated patients scheduled for laparoscopic surgery (cholecystectomy).

Therefore, this study was planned to compare I-gel with standard endotracheal tube regarding (a)Efficacy in controlling the airway for oxygenation and ventilation; (b) ease of insertion (c) hemodynamic changes and complications posted for laparoscopic cholecystectomies.

AIMS AND OBJECTIVES

AIM

The aim of the study to compare the efficacy of I-gel and endotracheal tube in patients undergoing elective laparoscopic cholecystectomy.

OBJECTIVES

The objective of the study is to compare the endotracheal tube with I-gel as an airway device for patients undergoing elective laparoscopic cholecystectomy surgery and to compare the cardiovascular stability provided by both devices throughout the procedure.

The following points will be considered for the comparison: -

1. Ease of insertion I-gel compared to the endotracheal tube.
2. Ease of insertion of gastric tube in I-gel compared to the endotracheal tube.
3. Hemodynamic changes.
4. Changes in peak airway pressures.
5. Postoperative complications.

SAMPLE SIZE CALCULATION

$n= 2*[z_{\alpha}+z_{1-\beta}]^2*SD^2/d^2$

Z_{α} =1.96 at 5% level of significance

$Z_{1-\beta}$=0.842 at 80% power

SD=standard deviation

d= effect size

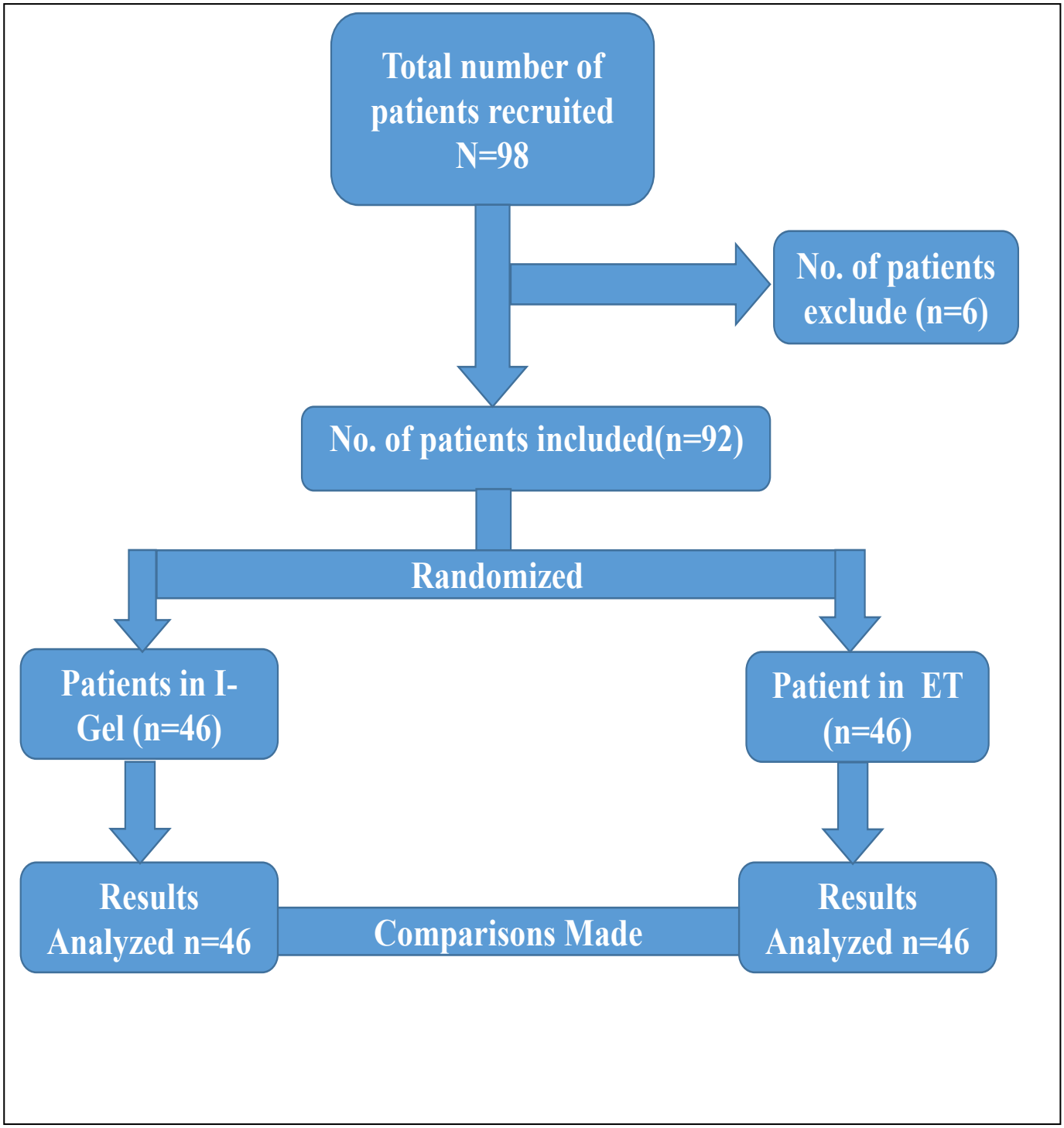
In reference to the article "Maharjan SK. The hemodynamic and ventilator responses wit, i-gel, laryngeal mask airway and tracheal intubation during laparoscopic cholecystectomy. Journal of Kathmandu Medical College, Vol. 1, No. 2, Issue 2, Oct.-Dec., 2012."

SD=5.0, d=2.9

After putting the values in the above-mentioned formula, and adding 10 % dropout rate n=92, n= 46 in each group.

Group I – Patients receiving I -gel as airway device (n = 46)
Group E – Patients receiving endotracheal tube as airway device (n =46)

Flow Chart of the Study Design



Review of Literature

The most common anesthetic technique in laparoscopic cholecystectomy is general anesthesia with controlled ventilation which is often achieved with the help of an endotracheal tube (ETT) which is considered a gold standard procedure. During laparoscopic cholecystectomies, high intra-abdominal pressures due to carbon dioxide insufflation increase the risk of passive gastrointestinal regurgitation and carbon dioxide retention. For these reasons, cuffed ETT is the most preferred technique when considered in terms of airway protection.

The protection of a patient's airway is highly essential in general anaesthesia, resuscitation, and critical and emergency care as well. A recent study from the UK suggested that out of an estimated 1.1 million procedures, about 38.4% of procedures done under general anesthesia implemented endotracheal intubation as the technique for airway management every year.(10)

In general, difficulties during intubation are one of the most common airway management problems. However, the most frequently encountered problems in outpatient settings include delayed intubation, misplaced tracheal tubes, or airway trauma that can also cause death or hypoxia-mediated brain death. On the other hand, intubation separates the respiratory and digestive tracts, allows for breathing control, and simplifies the delivery of oxygen, anesthetic gases, and medications.

In typical Endotracheal intubation, after the anesthesia is given, a flexible plastic tube is placed into the trachea through the orotracheal or the nasotracheal route to help maintain the patient's ventilatory parameters and help the patient to breathe. Several techniques are available including direct laparoscopy or video laparoscopy, for the direct placement of an endotracheal tube into the trachea and fiber optic visualization of the vocal cords either by nasal or oral routes.

Poor respiratory drive, doubtful airway patency, hypoxia, and hypercarbia are just a few of the many indications for endotracheal intubation. These symptoms are determined by assessing the patient's mental state, potential airway compromises, level of awareness, respiratory rate, respiratory acidosis, and oxygenation level. A

Glasgow Coma Scale of 8 or less is typically a sign that an intubation is necessary in a trauma situation.(11)

As with any other procedure, the advantages and disadvantages of endotracheal intubation should be weighed. Due to extensive bleeding or disruption of the architecture of the upper airway and the face, severe orofacial damage can prevent oropharyngeal intubation. Additionally, cervical spine manipulation during intubation can be hazardous to patients who have spinal injuries and are immobile. If the clinical circumstance permits, other techniques of breathing and oxygenation should be used in these clinical settings. If a permanent airway is required, one should be ready for the possibility of a surgical airway. While there are no objective reasons to avoid intubation, the choice to establish a permanent airway should be based on the clinical circumstances of each patient. (11)

Failure to intubate the trachea occurs 1-3 times per 1000 attempts.(12) A range of clinical tests and models have been described to anticipate difficult laryngoscopy and intubation. Most prediction models use Cormack-Lehane laryngoscopic views, which divide the glottis into four grades (Figure 1.) based on the clarity in view acquired are as follows:

Grade I – Completely visible glottis
Grade II - Posterior Commissure visibility
Grade III – Visibility of the Epiglottis tip alone
Grade IV – Hardly visible structure of the glottis

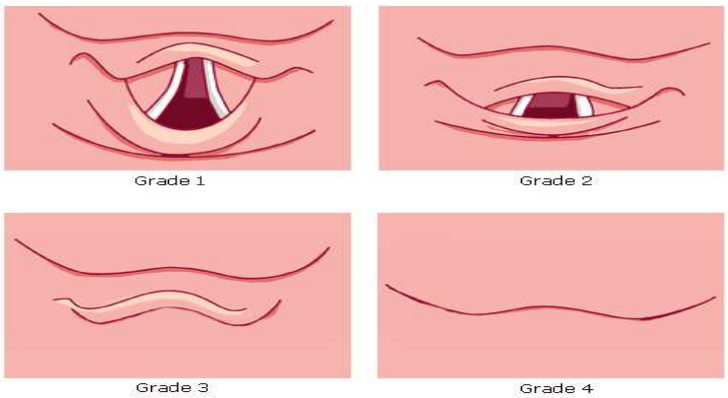


Fig.1. Cormack- Lehane views

Based on the above-given classifications, grades III and IV are called difficult intubations and are directly termed as higher Cormack-Lehane views.

Several studies have sought to discover qualitative or quantitative airway evaluation measures that predict intubation difficulty or ease. Some of the observable signs of such problematic airway management include the limitation in the mouth opening, thyromental distance found shorter (6 cm), and swollen or enlarged maxillary incisors with incomplete extension possibilities of the neck. However, the efficacy of these predictive screening tests has been arising due to the low positive predictive value. The predictive values of the patients can be improved when the patient is able to encompass his/her neck at the craniocervical connection.(13)

Additionally, tests for assessing the adequacy of the oropharynx for laryngoscopy and intubation are there: the Mallampati grading test. (14) To do the Mallampati grading test, the patient needs to be rested in a seated position with a neutral position of the head, and a widely opened mouth extended to its utmost position. The degree to which the base of the tongue obscures pharyngeal structures has been classified as follows:

CLASS I: visualizing soft palate and the uvula

CLASS II: visualizing soft palate and tonsillar pillars

CLASS III: visualizing the soft palate alone

CLASS IV: visualizing hard palate alone

However, a meta-analysis study has reported that the Mallampati grading test is not good for predicting airway difficult situations alone on the other hand it is more beneficial on combining with other factors such as dentition, thyromental distance, and neck extension.(15) Some of the common visible vectors that can be used for measurements and thereby align the oropharyngeal line for direct laryngoscopy includes the opening of the mouth, protrusion of the mandibular region, thyromental distance, and mobility of neck.

Endotracheal tube (ETT)

The endotracheal tube (ETT) was first reliably used in the early 1900s.(16) Endotracheal tubes are generally made up of polyvinyl chloride (PVC), and silicone, and are less commonly made up of red rubber. PVC tubes are preferred as they are inexpensive, nontoxic, thermolabile, transparent, and smooth. PCV tubes have a radio-opaque longitudinal line for visualization on the radiography. They should be used as a use-and-throw device. ETT made up of silicone is -autoclavable and therefore reusable. Red rubber EET is seldom used today as they are associated with a more toxic reaction. Endotracheal tube development has followed anaesthetic and surgical development closely.(17) Improvements have been achieved to reduce aspiration, isolate a lung, deliver drugs, and stop airway fires.

Components of an Endotracheal tube:

The Tube

The endotracheal tube has a length and diameter. Internal diameter in millimeters is what is meant by the endotracheal tube size (mm). The ETT will typically list both the inner diameter and outer diameter of the tube (for example, a 6.0 endotracheal tube will list both the internal diameter, ID 6.0, and outer diameter, OD 8.8). Greater gas flow resistance is associated with narrower tubes. As a result, one should choose the largest tube that is suitable for the patient. The ETT is marked in standard intervals of 2 cm and is measured from the distal end of the tube. The depth of the endotracheal tube that ends at the patient's teeth or lips is measured following a successful intubation. In order to make sure that the tube has not migrated outside of the trachea or further in during patient movement or transport, this depth measurement serves as a baseline. PVC is not radiopaque, and thus a radiopaque linear material is included throughout the length of the tube to make it easier to visualize the placement on an x-ray. Ideally, the distal tip of the ETT is 4 cm (+/- 2 cm) above the carina on chest x-ray in adults.(18) To perform bronchoscopy on an adult patient using a conventional bronchoscope (5.7 mm in diameter with a 2 mm suction channel), the patient must normally be intubated using an ETT that is at least 7.5 to 8.0 size; larger ETTs are available and can be utilized for bronchoscopy.(19) The average endotracheal tube depth is 23 cm for men and 21 cm for women, measured at the central incisors. The average tube size for an adult male is 8.0, and for an adult female is 7.0, though this

varies depending on the institution. Pediatric tubes are sized using the equation: size = ((age/4) +4) for uncuffed ETTs, with cuffed tubes being a one-half size smaller.(20) Typically a pediatric ETT is taped at a depth of 3 x the tube size in a child (i.e., a 4.0 ETT commonly gets taped at around 12cm depth).

The Cuff

It is an inflatable balloon at the distal end of the endotracheal tube. It was Arthur Guedel who introduced the first EET cuff, he tried his prototype cuff on animal tracheas, encouraged by his colleague Ralph Walters who wanted something to seal the tracheal to prevent gas from escaping while using Walter's to and-fro Co2 absorber canister during positive pressure ventilation. Pediatric ETTs are produced with and without cuffs. Some ETTs have a low-volume high-pressure cuff (LPHV), but it is more common to find high-volume low-pressure cuffs (HPLV) on ETTs in current medical practice.(21)

Advantages and disadvantages of high-pressure low volume cuff:

- Better protection against aspiration as they expand uniformly without any channels.
- Lower incidences of sore throat.
- Keeps the tip of the ETT central in the trachea.
- Main disadvantage is that it has a smaller contact area with the trachea and with pressure areas it deforms the tracheal shape, which may become ischemic.

Advantages and disadvantages of low-volume high-pressure cuff:

- More of the cuff is in contact with the trachea so the pressure is spread across the surface area.
- Less pressure on the trachea resulting in fewer post-operative complications secondary to cuff pressure.
- major disadvantage is there are folds in the cuff wall that allow fluid leakage into the lung causing infection and longer hospital stays.

Intracuff Pressure

The cuff should seal the airway without putting too much pressure on the trachea, which could impair its blood flow or cause the trachea to enlarge. Most authors suggest that in normotensive individuals, the pressure on the lateral tracheal wall measured at end-expiration should be between 25 and 34 cm H2O (18 to 25 mm Hg) (22,23). A patient who needs high peak inflation pressures will require a higher minimum occlusive pressure (cuff pressure) to prevent leaks, which raises the risk of ischemic tracheal damage(24). Although no specific cuff pressure guidelines for children have been made, it makes sense to utilize lower pressure because of their lower artery pressures (25).

Means to Limit Cuff Pressure

The cuff can be inflated or deflated as necessary to change the cuff pressure, which can be measured continuously or at regular intervals. This is the only approach to provide sufficient defense against the risks of aspiration and tracheal ischemia (26). Measurement is simple, and cuff monitors are reasonably priced. When the cuff pressure is not measured, it is typical for pressures to be either higher or lower than required. When utilizing nitrous oxide, it can take four hours to stabilize the cuff pressure (27). To prevent a leak in the postoperative phase, the cuff should be drained and inflated with air if the tracheal tube is to be left in place and nitrous oxide has been used (28). Numerous techniques have been employed to continuously or sporadically monitor intracuff pressures (29,30). An air-filled pressure transducer (31)or a manometer can be used to directly link the inflation tube to the pressure channel of a monitor to measure cuff pressure (32).

Pilot Balloon

The pilot balloon (bulb, external reservoir, external balloon) may be located near the midpoint of the inflating tube or adjacent to the inflation valve. Its function is to indicate cuff inflation.

Inflation Valve

The inflation valve is designed so that when the tip of a syringe is inserted, a plunger is displaced from its seat and gas can be injected into the cuff. Upon removing the syringe, the valve seals so that gas cannot escape from the cuff.

The Bevel

An angle or slant at the distal end of the ET tube is known as the bevel. Bevel facilitates the placement of the Endotracheal tube through the vocal cords and provides improved visualization, left facing Bevel provides an optimal view.

The Murphy's Eye

It is present at the distal tip at the distal lateral wall of the et tube. It is a safety mechanism in case the distal end of the ETT should become obstructed by the wall, contact with the Carina, or due to blockage formed due to secretions over time, gas flow can still occur via Murphy's eye, thus preventing complete obstruction of the endotracheal tube.

The Connector

The connector attaches the ETT endotracheal tube to the ventilator breathing circuit or an Ambu bag. A Universal 15 mm connector is present in all ET tube.

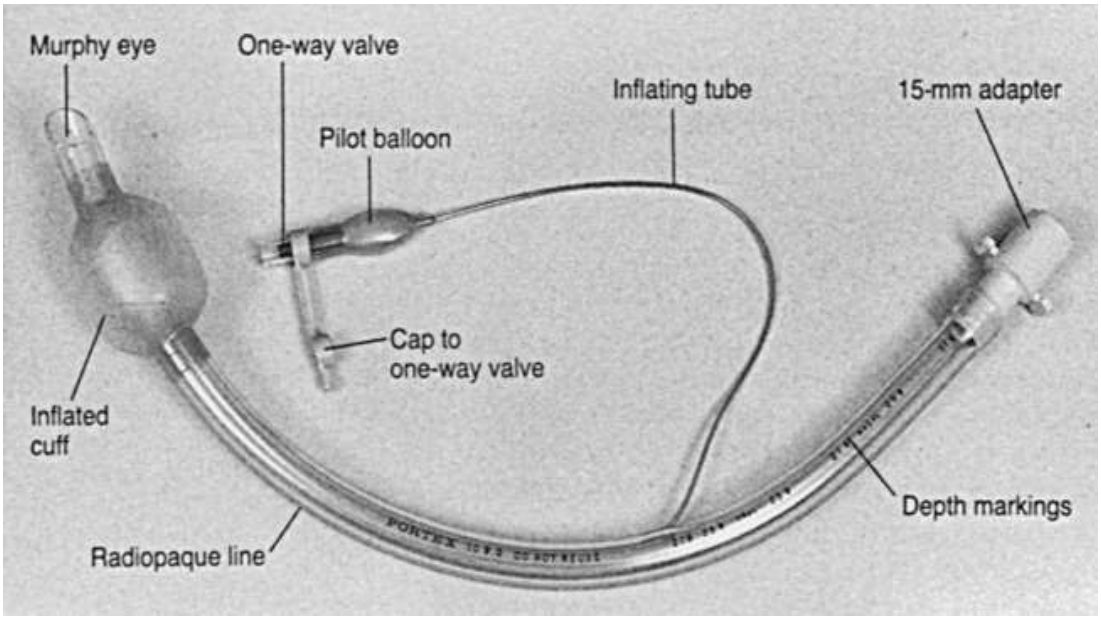


Fig 2. Endotracheal tube

Considering the boundaries behind any one technique, several generations of Supraglottic airway devices have been discovered and are a well-known alternative to endotracheal intubation for various surgeries including laparoscopic surgeries. Supraglottic airway devices (SAD) were developed by Dr. Archie Brain, a British anesthesiologist. The first supraglottic airway device - the Laryngeal Mask Airway (LMA) evolved from a combination of a nasal mask attached to a tracheal tube. since following the success of the LMA several SADs have been introduced some have prevailed while others have dwindled into oblivion.(33)

CLASSIFICATION OF SUPRAGLOTTIC DEVICE: (33)

BASED ON GENERATION:

FIRST GENERATION DEVICES	**SECOND GENERATION DEVICES**
-Simple airway devices - Low-pressure pharyngeal seal. - May or may not protect from aspiration	-Airway devices with additional gastric channel (reduces the risk of aspiration) -Specially designed for safety - High-pressure pharyngeal seal -Maybe more efficacious in ventilation
-The Laryngeal Mask Airway (Classic LMA). -Flexible LMA. - All laryngeal masks - SLIPA - Cobra Peri laryngeal Airway.	-Proseal LMA. - I-GEL, -Laryngeal Tube suction II -LMA Supreme. - combitube - Baska mask

BASED ON NO OF LUMEN:

Single lumen devices	C LMA, LMA -flexi, LMA -Unique, ILMA, Ambu laryngeal mask, C-Trach, Cobra, SLIPA, Laryngeal Tube, COPA (cuffed oropharyngeal airway. Air-Q Intubating Laryngeal mask
Double lumen devices	Proseal LMA, Combitube, Airway, Laryngeal Tube suction / sondum (LTS). Management Device (AMD), Baska Mask.
Triple lumen devices	Elisha Airway Device (EAD)

BASED SEALING MECHANISM:

Cuffed peri laryngeal sealer	**Cuffed pharyngeal sealer**	**Cuff less preshaped sealer**
Non directional non esophageal sealers CLMA, ILMA,Soft seal. • Directional non esophageal sealing- FastrachLMA, ALMA. • Directional sealers: PROSEAL LMA	Without esophageal sealing – COPA, PAX. • With esophageal sealing – Combitube, LT, LTS	• With esophageal sealing – I –GEL, BASKA • Without esophageal sealing – SLIPA, AIRQ

FEATURES OF AN IDEAL SUPRAGLOTTIC AIRWAY DEVICE: (33)

1. It can be used during both spontaneous and positive pressure ventilation; an efficient seal of the upper airway is a must.
2. Low resistance to gas flow.
3. Protects airway from upper airway secretions and GIT contents.
4. Incidence of airway morbidity and adverse events are low.
5. It is easily accepted by the oropharynx in shape, material, cuff volume, and cuff position.

ADVANTAGES OF SUPRAGLOTTIC DEVICE:

- Less stimulation of the sympathetic system leads to lower hemodynamic instability.
- Patient tolerates the device even in the light plane of anaesthesia.
- Ease of insertion and smooth removal.
- Avoidance of laryngoscopy and muscle relaxant.
- They do not displace bacterial colonies from the oral or nasal to the lower respiratory tract.
- In case of cannot ventilate, or cannot intubate situation it is used as a life-saving device in securing the airway.
- Less injury to the airway compared to ETT.
- Pollution in the operating room is less compared to a face mask.
- Recovery and emergence time is less.

DISADVANTAGES AND CONTRINDICATION OF SAD:

- It does not provide protection against aspiration so contraindication in full stomach patients. (True for 1st generation SAD).
- Not useful in patient with glottis, supraglottic obstruction, Oral and cervical pathology like large goiter, tumor.
- It is not a definite airway.
- Patient with poor lung compliance cannot be recommended as it needs high inflation pressure.
- Patient with less mouth opening is not a candidate for SAD placement.

INDICATIONS OF SAD:

- Elective surgeries like short elective surgical procedure as an alternative to ETT intubation.
- Anticipated and unanticipated difficult airway.
- Indicated in situation where one cannot ventilate and cannot intubate.
- As an alternative to ETT intubation during CPR in cardiac arrest.
- As conduit for ETT insertion when difficult intubation occurs.
- Useful in radiation therapy, diagnostic and interventional radiology, ECT, endoscopy.
- As a bridge for extubating.
- Ophthalmic, neurosurgery, unstable cervical spine, supplementing regional block – useful in above procedures.

Anatomy and Physiology of Upper airway:

The oral cavity and pharynx, which include the larynx, nasopharynx, oropharynx, and hypopharynx, make up the upper airway. These structures warm and humidify the air, and they receive blood from the internal and external carotid arteries. While the facial nerve and glossopharyngeal nerve innervate the oropharynx, the trigeminal nerve offers sensory innervation to the mucous membranes of the nasopharynx.(11)

The pharynx is made up of a broad tube of muscles and fibrous tissue that forms the common pathway of the airway and gastrointestinal tract. It comprises of three divisions – the nasopharynx, the oropharynx, and the laryngopharynx.

The nasopharynx extends from posterior nasal cavity in base of skull up to the soft palate. The function of the nasopharynx is primarily to transfer inhaled gases from nostrils to the lungs. The oropharynx begins after the soft palate and ends at the beginning of epiglottis.

The laryngopharynx or hypopharynx begins from epiglottis and ends at the inferior border of the cricoid cartilage. Here it tapers and continues as esophagus. This is the portion of pharynx that is related to the insertion and seat of the SADs.

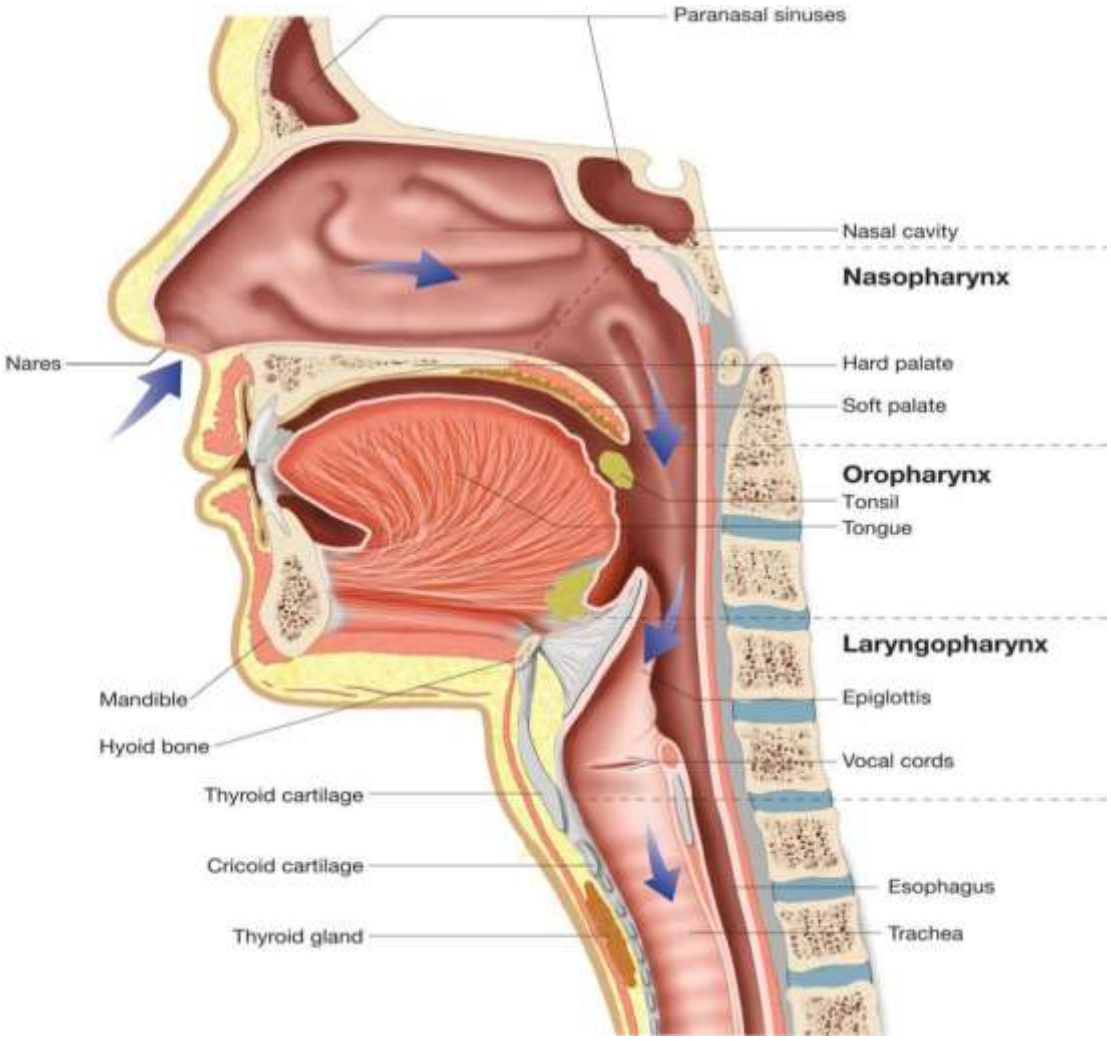


Fig. 3. Anatomy of Airway

The laryngopharynx or hypopharynx begins from the epiglottis and ends at the inferior border of the cricoid cartilage. Here it tapers and continues as the esophagus. This is the portion of the pharynx that is related to the insertion and seat of the SADs. When a person is given general anesthesia in a supine position, the airway gets obstructed due to loss of muscle tone of pharyngeal muscles and the tongue fall. The SADs provide an effective measure of relieving obstruction of the airway.

Laryngeal Cartilages:

The larynx is made up of nine cartilages- three unpaired and three paired ones. The unpaired are the thyroid, cricoid, and epiglottis. The corniculate, the arytenoids, and the cuneiforms are paired. The function of SAD is dependent on the epiglottis in this regard.

Larynx Cavity:

The laryngeal cavity lies between the laryngeal inlet to the inferior border of the cricoid cartilage. It has two folds – the upper vestibular folds, or the false vocal cords, and the lower vocal cords, or the true vocal cords. The Rima glottidis, often known as the glottis, is the space between the real vocal cords. The pyriform sinus is the part of the larynx lying on either side of the aryepiglottic fold.

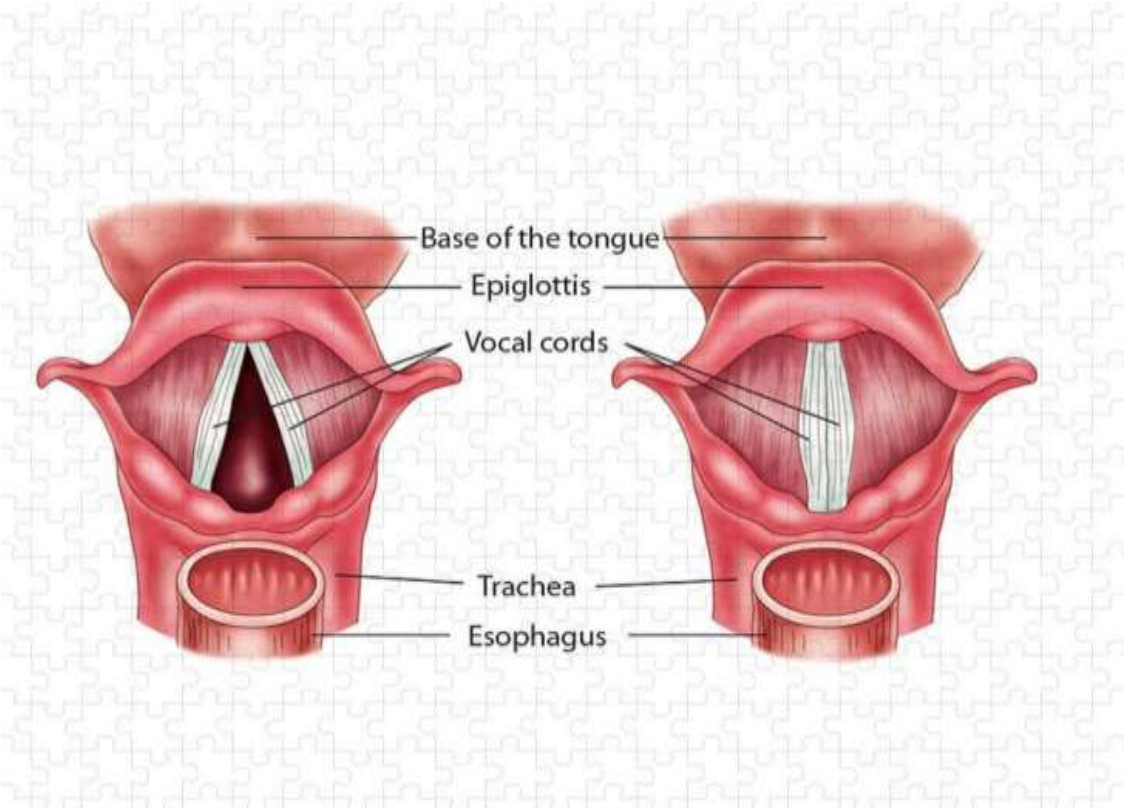


Fig.4. Anatomy of Larynx

Epiglottis:

The epiglottis is a leaf-shaped unpaired cartilage of the larynx that functionally separates the oropharynx and laryngopharynx. It is attached to the lower end of the thyroid cartilage by the epiglottic ligament. The upper part of the epiglottis is free and is covered by a mucous membrane. The depressions on either side of the median epiglottic fold is called the vallecula. It is a common site for foreign body lodgment. The epiglottis prevents aspiration by covering the glottis during swallowing. The most common airway structure interferes with the proper placement of the SADs.

Trachea:

The trachea has cartilaginous rings anteriorly and a soft, membrane posterior portion. The range of adult tracheal diameters is 15 to 20 mm. These characteristics serve as crucial clinical indicators that separate the trachea from the esophagus and enable the use of a bougie for intubation. The trachea splits into the right and left mainstem bronchi near the fifth thoracic spine. Foreign object dislodging into the left mainstem bronchus is less likely because of the more acute angle between the trachea and the left mainstem bronchus. If the endotracheal tube is advanced too far distally, the obtuse angle between the trachea and the right mainstem bronchus renders it more susceptible to right mainstem intubation.(11)

The vagus nerve's superior laryngeal branch, which also supplies afferent innervation to the tongue base and vallecula, innervates the larynx, which is located above the voice cords. Direct laryngoscopy causes circulatory alterations that are influenced by these vagal fibres. The landmark for emergent cricothyrotomy is the cricoid cartilage, which is ring-shaped and located inferior to the cricothyroid membrane. Vocal cord visibility during intubation is frequently made easier through identification of the cricoid cartilage and airway manipulation. The hyoepiglottic ligament inserts at the base of the vallecula and connects the hyoid bone to the larynx. In order to expose the vocal cords during intubation, this ligament assists in lifting the epiglottis anteriorly.(11)

I-GEL

A latex-free, sterile, single-use device, made of a soft gel-like, transparent medical-grade thermoplastic elastomer called styrene ethylene butadiene styrene. The gel-like mask creates an anatomical seal of the pharyngeal, laryngeal, and peri-laryngeal structures. The oropharyngeal seal pressure created is effective for both spontaneous and controlled ventilation. It creates an anatomical seal without an inflatable cuff. So, it avoids the compression injury to peri laryngeal structures that can occur with another inflatable device. It is more stable, easier to introduce, and causes less tissue stress. It is a conduit that can be utilized for endotracheal intubation(34).

Components and their functions:(35)

Soft non-inflatable cuff

The soft non-inflatable cuff fits snugly onto the peri laryngeal framework, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, peri-thyroid, peri-cricoid, posterior cartilages, and spaces. Each receives an impression fit, thus supporting the seal by enveloping the laryngeal inlet. The tip separates the esophageal aperture from the laryngeal inlet by being in the proximal entrance of the esophagus. The outer cuff form helps to prevent neurovascular compression by ensuring that blood flow is maintained to the laryngeal and peri-laryngeal framework. In order to fit snugly into the possible space of the peri laryngeal pouch, it becomes narrower and deeper as it moves through the pharyngo-epiglottic folds, generating an outward movement.

Gastric channel:

From its proximal opening at the side of the flat connector wing to the distal tip of the non-inflatable cuff, the gastric channel extends across the entire device. The device's distal tip fits anatomically into the upper esophageal orifice, and the distal opening of the gastric channel allows a nasogastric tube to flow through to empty the contents of the stomach and can help with gas venting from the stomach. Regurgitation can also be detected early due to the gastric channel. The gastric channel is not present in size one i-gel.

Epiglottic rest:

It is a protective ridge that aids in preventing down-folding or obstruction of the airway's distal entrance by the epiglottis. The device is prevented from migrating upward out of position and the tip from moving out of the upper esophagus by the epiglottic ridge at the proximal end of the bowl resting against the base of the tongue.

Buccal cavity stabilizer:

It is a built-in natural curvature and an inherent ability to adapt its shape to the oropharyngeal curvature of the patient. It is widened and concaved which helps to eliminate the potential for rotation, thus reducing the risk of malposition. It also provides vertical strength which aid in the insertion of the device.

15mm connector:

I-gel is equipped with a standard 15mm connector which provides connection to the anaesthetic system or patient connection. An integral bite block – this function is provided by the distal end of the connector, which runs through the center of the proximal part of the buccal cavity stabilizer. The junction of the distal tip to the body of the connector is V-shaped, which reduces the possibility of airway channel occlusion and significantly reduces the risk of kinking. A horizontally positioned black line marks the integral component of the bite-block, designating the ideal position of the teeth while the device is in place. The integrated bite block has information on the size and suggested weight.

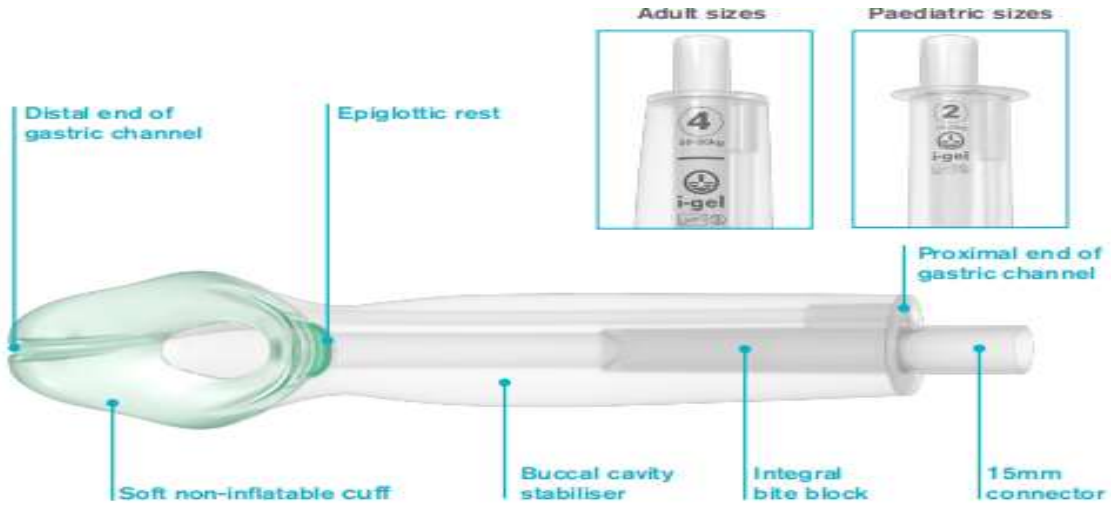


Fig .5. Components of I-gel

Sizing guidelines for the I- GEL supraglottic airway:

i-gel size	Patient size	Patient weight guidance (kg)
1	Neonate	2-5
1.5	Infant	5-12
2	Small paediatric	10-25
2.5	Large paediatric	25-35
3	Small adult	30-60
4	Medium adult	50-90
5	Large adult+	90+

Sizing appropriate size of nasogastric (NG) tube.

i-gel size	Maximum size of Nasogastric Tube (FG)
1	N/A
1.5	10
2	12
2.5	12
3	12
4	12
5	14

Sizing guidelines for inserting an ETT through an I – GEL supraglottic airway

i-gel size	Maximum size of Endotracheal Tube
1	3.0mm
1.5	4.0mm
2	5.0mm
2.5	5.0mm
3	6.0mm
4	7.0mm
5	8.0mm

INSERTION METHOD:

- Patient should be in sniffing position.
- Lubricate the I-GEL with gel.
- Hold the device firmly along the bite block.
- The cuff should face towards the chin of the patient.
- The soft mask is inserted into the mouth towards the hard palate and advanced downwards, backwards until a definitive resistance is felt.
- The black line marked on the bite block corresponds to the teeth indicates correct placement of the I GEL and its correct seal to peri laryngeal anatomy.

Relevant studies

In Elective Laparoscopic Gynecological Surgeries Under General Anesthesia, Sushant Dhawan et al. (2019) compared I-GEL and Endotracheal Tube and discovered that the ease of insertion and the number of attempts were comparable, but the time of insertion was less with I-Gel, with the results being statistically significant. The incidence of postoperative complications and the increase in hemodynamic parameters from baseline were both higher in patients with endotracheal tubes intubated, leading researchers to the conclusion that I-Gel requires less time for insertion with less hemodynamic change than endotracheal tubes. Additionally, I-Gel offered equivalent positive-pressure breathing to that of an endotracheal tube. I-Gel can therefore be regarded as a secure and appropriate substitute for an endotracheal tube for laparoscopic procedures. (36)

In a study comparison of proseal LMA, I-gel, and endotracheal tubes during laparoscopic cholecystectomy, Ravindra Kumar Gehlot et al. (2018) found that the I-gel group (10%) required considerably fewer attempts than the PLMA (13.3%) and ET tube (36.7%) groups ($p=0.019$). In comparison to the i-gel and p-lma groups, laryngopharyngeal morbidity was considerably higher in the et tube group($p<0.05$). It was determined that Supraglottic Airway Devices (PLMA and I-gel) were as effective as ET tubes in establishing airways and that the hemodynamic stability is better than ET tubes in laparoscopic cholecystectomy. Hemodynamic changes were significantly higher in the et tube group immediately after intubation, which persisted for 3 minutes, and immediately after extubating ($p=0.00$).(37)

I-Gel and endotracheal tubes were compared by Lai et al. (2017) in the laparoscopic pneumoperitoneum and Trendelenburg positions, and it was shown that there were no variations in the leak fraction between the two groups. Significantly reduced leakage was seen in the i-gel group in the LPT position compared to the supine position. In the ETT group, this phenomenon was not seen. Additionally, the I-gel group's postoperative sore throat incidence was considerably lower than that of the ETT group. After extubating, none of our patients had any aspiration-related symptoms or vomitus. Considering this, the study concluded that I-gel is an acceptable substitute for an ETT in non-obese individuals undergoing procedures with LPT positioning.(38)

In patients undergoing laparoscopic surgery, Park et al. (2016) examined supraglottic airway devices and endotracheal tubes, and they found no differences in the insertion success rate on the first attempt, insertion time, or oropharyngeal leak pressure. Additionally, there were no intergroup variations in the prevalence of desaturation, stomach insufflations, regurgitation, or aspiration. However, the ETT group had a higher incidence of laryngospasm, cough at removal, dysphagia or dysphonia, sore throat, and hoarseness than the SGA group did. concluded that the ETT group had a higher incidence of laryngospasm, cough at removal, dysphagia or dysphonia, sore throat, and hoarseness than the SGA group did. The rate of first-time insertion success, insertion time, OLP, and other problems did not differ between the groups, though.(39)

In laparoscopic operations, Badheka et al. (2015) compared I-gel to endotracheal tubes and discovered that using an ETT caused a substantial rise in mean blood pressure and pulse rate during insertion. Additionally, compared to ETT, the time needed for I-gel insertion was noticeably shorter. It was determined that I-gel required less time for insertion with fewer hemodynamic changes than ETT because of the ease and number of efforts for inserting an airway device, attempts for inserting a stomach tube, and the effectiveness of ventilation was comparable between the two groups. Comparable to ETT, I-gel also offers sufficient positive pressure ventilation. indicated that I-gel could be a secure and appropriate substitute for ETT in laparoscopic procedures.(40)

In a study conducted by M Z Abdullah et al (2015) on 150 ASA I and II non-paralyzed patients having quick operations under GA. I- gel greatly reduced the insertion time. With LMAS, the sealing pressure was better. When compared to LMAS, I-gel caused less sore throat.(41)

Ana M. Lopez et al. (2015) conducted a cross-over evaluation of Ambu aura gain, LMA supreme, and I-gel in 7 fresh cadavers without challenging airway requirements. Except for one LMA S case, which required modifying procedures for proper insertion, all devices were properly placed within three attempts. LMA S made the 16G gastric tube's passage simple. With I-gel, fiberoptic tracheal intubation was

simple. in less than 60 seconds. Lateral X-rays and neck dissections were done to confirm the optimal alignment of all devices with the respiratory and digestive tracts.(42)

In 60 patients undergoing elective procedures under GA, Surya Gowthami Katika et al. (2015) compared I-gel and LMA supreme. I-gel placement took more time on average than LMA S (p 0.0001). 93% of patients with LMA supreme had no trouble inserting it, compared to 57% with I-gel. I-gel was used to identify blood staining, while LMA Supreme was used to detect postoperative sore throat. Desaturation, tooth damage, or laryngospasm did not occur in either group.(43)

In a study conducted by Hyuk Kim et al. in 2014, 100 anesthetized and paralyzed youngsters were used to compare I-gel with LMA S. I-gel required more time to insert than LMA S (p=0.004). OPLP was higher in the I-gel than the LMA S (p=0.013). On a fiberoptic examination, 96% of the vocal cords in LMA S and 90% of those in I-gel could be seen. In comparison to LMA S, I-gel needed greater airway manipulations (p 0.001).(44)

I-gel and LMA classic were compared in 120 patients undergoing urologic operations under general anaesthesia without muscle relaxants by Reyhan Polet et al. (2014). The procedure was carried out by a single anesthesiologist who had experience with both devices and had a 5% first-time failure rate. Gastric regurgitation was discovered using the Methylene Blue technique. With I- gel, the insertion time was greatly reduced. For I-gel, the fiberoptic glottis vision was noticeably better. Incidence of sore throat 24 hours after the surgery did not differ between the two groups.(45)

I-Gel and Endotracheal Tube were compared by Samia M et al (2014) during laparoscopic surgeries on adult patients, and it was discovered that there was no statistically significant difference between the two in terms of heart rate, oxygen saturation, end-tidal CO2, and peak airway pressure changes. After placement in the I-gel group, mean arterial blood pressure became steadier. The number of insertions attempts and insertion duration differed significantly between the two groups as well. The ETT group had an easier time inserting the gastric tube than the other groups. The ETT group experienced more postoperative problems, including dysphagia, dysphonia, nausea, and vomiting. The amount of blood on the gadget was not different, though. The study found that I-gel was superior to the cuffed ETT in terms

of hemodynamic stability changes after insertion without changing gas exchange parameters and was a safe airway device during laparoscopic surgeries. Although there were greater difficulties in the ETT group, the I-gel group had a harder time inserting the stomach tube.(46)

Maharjan SK et al (2012) compared the hemodynamic and ventilator responses with i-gel, laryngeal mask airway, and tracheal intubation during laparoscopic cholecystectomy and discovered that tracheal intubation resulted in the greatest hemodynamic changes and laryngeal mask airway resulted in moderate hemodynamic changes, while I-gel resulted in stable hemodynamics. In terms of ventilatory response, oxygenation and ventilation were well maintained, with maximum airway pressures of mean ± SD: 20.11 ±3.46, 20.24 ±4.42, 19.05±4.82 cmH2 O during carboperitoneum in the I-gel, laryngeal mask airway, and tracheal tube groups, respectively, and oxygen saturation of 98 to 100% and end-tidal co2 level of 31-35 mmHg. During carboperitoneum minute volume was well maintained in all groups. The study found that I-gel produced the least hemodynamic stress response of the three airway management devices used during general anesthesia with positive pressure ventilation and that both supraglottic devices can be used with proper size and placement with acceptable hemodynamics and ventilation during laparoscopic surgery.(47)

In the study 'Randomized comparison of the LMA S with I-gel in spontaneously breathing anesthetized adult patients' by Chew EE, Hashim NH, Wang CY (2010) ninety patients of ASA I & II were studied in a prospective randomized control study. The primary outcome measure was oropharyngeal leak pressure along with insertion success rate, ease of insertion, and incidence of complications. The mean oropharyngeal leak pressure for LMA S was 25.6 cm H2O which was greater than for I-gel 20.7cmH2O p=0.001. The overall insertion success rates were similar p=0.132. The incidence of complications was low in both groups. The grade of the fiberoptic view was better with the I-gel than the LMA S p=0.001.(48)

Joly N, Poulin LP, et al. (2011) conducted an RCT in 100 adult patients undergoing elective surgery under GA comparing I-gel with LMA S. In both groups, the devices

were successfully implanted in 92% of the patients. The mean leak pressures did not differ significantly. I-gel had a faster insertion time than LMA S (p=0.003). In terms of postoperative complications, there was no difference between the two groups.(49)

Mohamed Ibrahim et al. (2011) compared the use of I-gel and cuffed tracheal tubes during volume-controlled ventilation in elective laparoscopic cholecystectomy and discovered that there was no statistically significant difference in leak fraction between the two devices at 6 and 8 ml kg1 tidal volume prior to pneumoperitoneum. I-gel can be utilized as an alternate device to the endotracheal tube during VCV for laparoscopic cholecystectomy provided that peak pressure does not exceed leak pressure, according to significant differences reported after pneumoperitoneum at 8 and at 10 ml kg1.(50)

In 100 paralyzed patients undergoing gynecological laparoscopic surgery with controlled breathing, W.H.L Teoh, K. M. Lee et al. (2010) compared the LMA S vs. the I- gel. Oropharyngeal leak pressure did not differ between the two groups (p=0.18), and 94% of LMA S and 96% of I-gels were successfully inserted on the first try with comparable ease (p=0.4). With LMA S, inserting the gastric tube was simple and rapid.(51)

In a study conducted by V S Senthil Kumar et al. (2010) on 60 adult patients with an ASA grade of 1 or 2 who were undergoing elective surgery and receiving GA. LMA S's mean insertion time was substantially shorter than I- gel's ($p< 0.05$). The airway leak pressures between the two devices were comparable. LMA S had a higher first try success rate and easier insertion (p 0.05). The hemodynamic response was the same in both groups, with no discernible difference. In the LMA S group, postoperative sore throat was noticed, and in the I-gel group, blood staining was noted.(52)

After comparing the usage of I-gel and a cuffed tracheal tube during pressure-controlled ventilation, V. Uppal and G. Fletcher et al. (2009) discovered that there was no discernible difference in the leak fractions of the two devices at 15 and 20 cm H2O PCV. At 25 cm H2O, the median leak fraction difference was 0.02 (P value 0.014) and the median leak volume difference was 26.5 ml (P value 0.006). With any of the airway pressures used during PCV, there was no indication of stomach

insufflations, and it was determined that i-gel can be utilized as a viable substitute for a tracheal tube.(53)

In 2009 study by Srivatsava et al. examined I-gel and LMA SAD in 100 patients undergoing laparoscopic surgery who were randomly divided into two groups According to the study, LMA S had a greater first-time success rate for mechanical breathing and was easier to insert with much fewer difficulties.(54)

For procedures like thyroid surgery, tonsillectomy, and neck exploration requiring neck flexion and extension, Swathi Gupta et al. (2005) compared I-gel and LMA S in 60 children. The purpose of the study was to show how neck flexion and extension affected juvenile patients who were sedated but were still breathing on their own. With a manometer linked at the machine end, they measured OPLP. They had concluded that neck flexion markedly raised the leak pressure in both I-gel and LMA S. It was discovered that the OPLP was marginally higher in flexion and lower in extension. In flexion, ventilation deteriorated, which was visible from the declining tidal volume.(55)

MATERIALS AND METHODS

Study Design: Randomized prospective comparative study

Place of study: Department of Anesthesiology, Santosh Hospital, Ghaziabad

Duration of study: 1 year

Study groups:

Group I – Patients receiving I -gel as airway device (n = 46)

Group E – Patients receiving endotracheal tube as airway device (n =46)

INCLUSION CRITERIA:

1. ASA Grade I & II (both sexes)
2. Age group between 18 to 60 years.
3. All patients undergoing elective laparoscopic cholecystectomy under general anesthesia.

EXCLUSION CRITERIA:

1. Patients belonging to ASA grade 3 and grade 4.
2. Patients with a reported history of any pathology of the neck and the airway.
3. Patients with a cardiac, pulmonary, hepatic, renal, gastric, or neurological disorder.
4. Patient with any other contraindication to supraglottic airway.

METHODS OF STUDY: About **92** patients admitted for elective laparoscopic cholecystectomy under general anesthesia at Santosh Medical College and Hospital, Ghaziabad, UP, were enrolled in the study after taking approval from the institutional ethical committee of Santosh Deemed to be University, Ghaziabad, UP and informed consent from the patients as well.

PRE-ANAESTHETIC-CHECKUP: A thorough pre-anesthetic checkup was done for all the patients. A detailed history of the present illness and any relevant past history of the disease was recorded. Clinical examination of the respiratory system, cardiovascular system, and central nervous system with the vertebral and cervical

spine as done. Routine hematological, biochemical, and radiological investigations appropriate for the surgery were done. The patients who fulfilled the above inclusion criteria and with none of the exclusion criteria mentioned above were explained about the study. The patients were explained in detail about the procedure of general anaesthesia and all their queries and doubts will be answered to get their confidence and support. Written informed consent was taken.

PREMEDICATION: All the patients fasted overnight and will receive premedication with Tab Alprazolam 0.25mg HS and Tab Ranitidine 150mg HS.

ANAESTHETIC PROCEDURE: All patients treated with an intravenous line with 18/20 G cannula before arriving in the operating room. The anesthetic machine, breathing circuits, and monitors were properly checked beforehand. A full range of drugs and equipment including appropriate size laryngoscope blade, endotracheal tubes and appropriate size of I-gel was in hand. After the arrival of patients in the operation theatre a baseline pulse rate, blood pressure, electrocardiogram (ECG), respiratory rate, SpO2 were noted. After pre-oxygenation for 3 minutes, anaesthesia was induced with intravenous propofol 2 mg kg-1 and fentanyl 2 mcg /kg and vecuronium 0.1 mg kg-1 intravenously. I-gel was lubricated with a water-soluble jelly. Once adequate depth of anaesthesia was achieved, I-gel or endotracheal tube was inserted by anesthesiologist as per group allocation. Correct insertion and establishment of an effective airway was confirmed by capnography trace, normal thoracoabdominal movement, lack of gastric insufflation (by epigastric auscultation) and absence of gas leak. Whenever an effective airway with I-gel is not achieved, then device was removed and re-inserted. Two attempts of I-gel insertion were performed before the attempt is labeled as failure and endotracheal tube intubation was then placed to secure the airway. After fixing the I-gel gastric tube (Ryle's tube) was inserted through gastric channel in the I gel group and nasally in group endotracheal tube group. Anesthesia was maintained with isoflurane and nitrous oxide 60% in oxygen and top up doses of injection vecuronium bromide 0.01mg/kg as a muscle relaxant. The patients were mechanically ventilated using circle system to maintain the normocapnia. The oropharyngeal leak or seal pressure was determined by closing the APL (adjustable pressure limiting) valve and allowing a fresh gas flow of 3 L/min. Airway pressure at equilibrium or when there was audible leak from throat was noted.

The maximum pressure allowed is 40 cm of H2O. For standardization intra-abdominal pressure was maintained at 8-12 mm of Hg. Anaesthetic agents were stopped at the end of surgery. At the end of surgery, residual neuromuscular paralysis was antagonized with neostigmine 0.05 $mg.kg^{-1}$ and glycopyrrolate 0.01 $mg.kg^{-1}$. On the recovery of the patients, they were extubated after thorough oral suctioning and was taken to the post anesthesia care unit (PACU) and observed for up to 24 hours.

OBSERVATIONS: -

1. Ease of insertion of device was defined as "Easy": no resistance to insertion in pharynx in a 1st attempt, "Difficult": if resistance was encountered during placement, or requires >1 attempt. "failure": if could not be inserted in three attempts.
2. The Ease of insertion of gastric tube No.12 (Ryle's tube) through the SAD was recorded as Easy: as in first attempt; Difficult: if not inserted in 2 attempts. Correct placement was ascertained by aspiration of gastric contents or epigastric auscultation with injection of air.
3. Oropharyngeal leak will be assessed clinically by the audible leak at mouth or by the audible noise using a stethoscope placed just lateral to the thyroid cartilage.
4. Intraoperative, heart rate, Non-invasive blood pressure (Mean Arterial Pressure, MAP), Peripheral oxygen saturation (SpO2) and end-tidal carbon dioxide (EtCO2) were recorded before induction, after induction, at 1, 3 and 5 minutes after insertion of device, after achieving carboperitoneum, end of surgery and during removal of devices.
5. Peak airway pressures before and after carboperitoneum .
6. Post- operative complications (blood on airway device, sore throat, hoarseness of voice, nausea and vomiting 0-24 hrs. in the post-operative period).

Throughout the study, patients will be observed for any adverse effects like bradycardia, tachycardia (PR less than or more than 20% of pre-operative level respectively on two consecutive readings), hypo and hypertension (MAP less than or more than 20% of pre-operative level respectively on two consecutive readings),

respiratory depression ($SaO_2 < 90\%$) arrhythmias, bronchospasm and dryness of mouth and they will be managed conventionally.

STATISTICAL ANALYSIS:

The data collected during the study was compiled using a Microsoft Excel spread sheet and analyzed statistically using the statistical package for the MedCalc statistical Software version 20.115 for window editions. Qualitative data were presented as number, percentage and Quantitative data were presented as mean±SD and median. Comparison between groups was done by $\chi 2$-test, fisher exact test, unpaired t test. P value less than 0.05 was considered to be statistically significant.

OBSERVATIONS AND RESULTS

Table 1: DISTRIBUTION ACCORDING TO AGE

Age (yrs)	Group I		Group E	
	N	%	N	%
21-30	10	21.74	10	21.74
31-40	15	32.61	16	34.78
41-50	16	34.78	13	28.26
51-60	5	10.87	7	15.22
Median	38		38	
Range	21-56		21-56	
Mean±SD	38.63±9.82		38.71±9.54	
t & p value	0.043, 0.965 (NS)			

Unpaired t test

CHART 1: DISTRIBUTION ACCORDING TO AGE

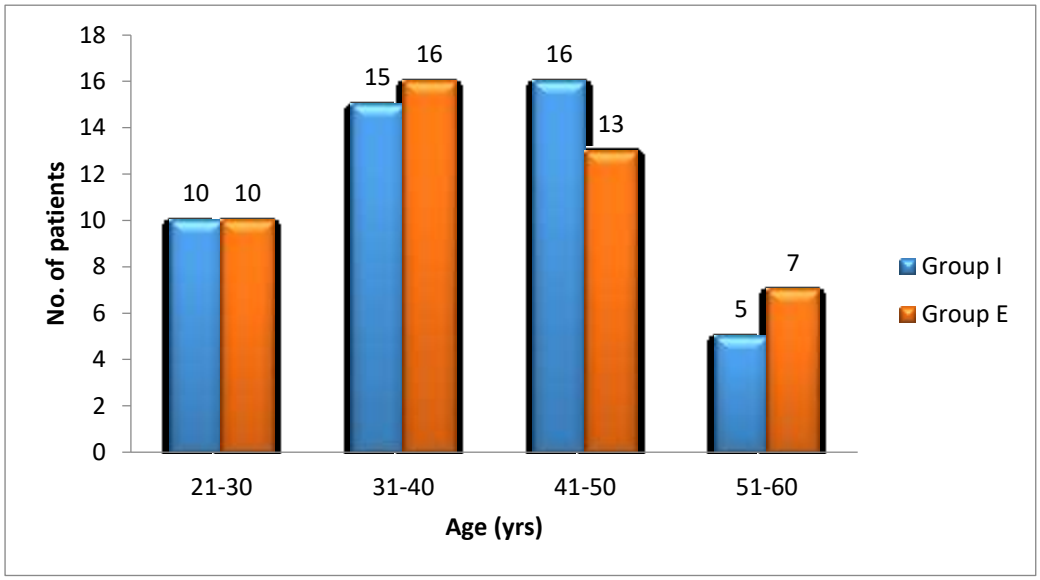


Table 1 shows distribution according to the age group and the data is analyzed using unpaired t test. The mean age group of patients in Group I was 38.63± 9.82 and the mean age in Group E was 38.71±9.54. The two groups were comparable with respect to age as the difference was not statistically significant as p value is 0.96 and t value is 2.01. Most patients were in between 21-56 years.

TABLE 2: DISTRIBUTION ACCORDING TO SEX

Gender	Group I		Group E	
	N	%	N	%
Male	16	34.78	11	23.91
Female	30	65.22	35	76.09
Total	46	100.00	46	100.00

Chi square 1.311, P value 0.252 (NS)

CHART 2: DISTRIBUTION ACCORDING TO SEX

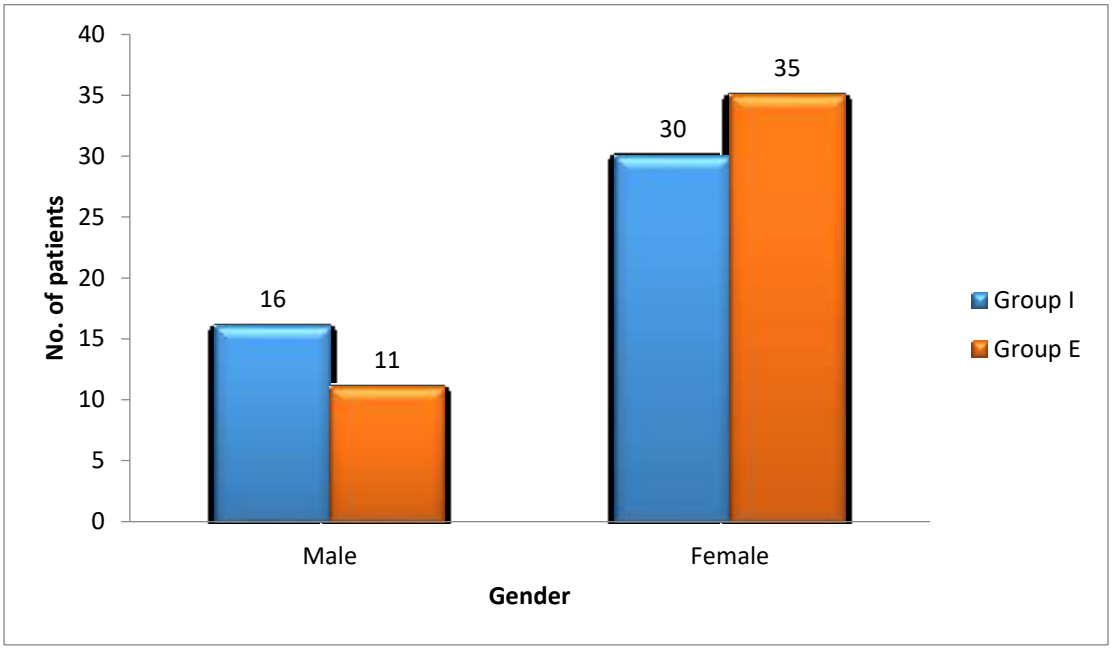


Table 2 shows distribution according to sex and the data is analyzed using chi square test. Out of 46 patients in Group I, 16 (34.8%) were males and 30 (65.2%) were females. In Group E out of 46 patients 11(23.9%) were males and 35(76.1%) were females. When compared the difference between the two groups it was found not to be statistically significant as p value is 0.252.

TABLE 3: DISTRIBUTION ACCORDING TO ASA GRADING

ASA Grade	Group I		Group E	
	N	%	N	%
I	35	76.09	38	82.61
II	11	23.91	8	17.39
Total	46	100.00	46	100.00

Chi square 0.597, P value 0.439 (NS)

CHART 3: DISTRIBUTION ACCORDING TO ASA GRADING

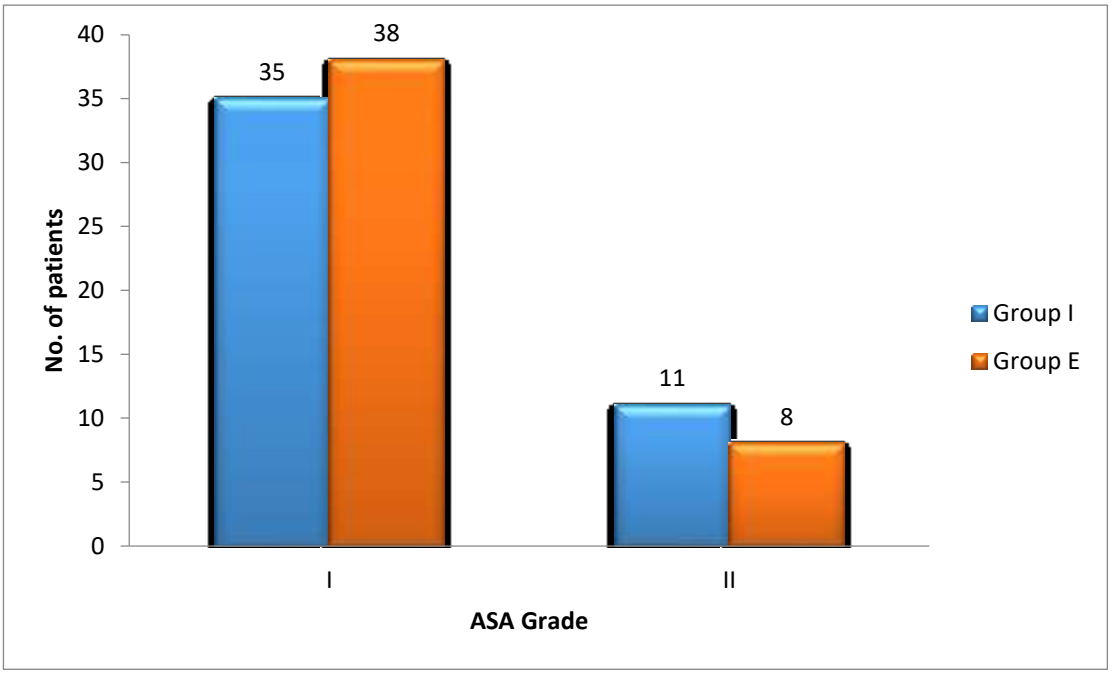


Table 3 demonstrates distribution according to ASA grading and data is analyzed using chi square test. In group I, 35 patients belonged to ASA Grade I and 11 patients in ASA Grade II, whereas in Group E, there were 38 patients in ASA Grade I and 8 patients in ASA Grade II. The difference in both the groups were not statistically significant as p value is 0.439.

TABLE 4 : DISTRIBUTION ACCORDING TO MPG GRADING

MPG Grade	Group I		Group E	
	N	%	N	%
I	24	52.17	20	43.48
II	22	47.83	26	56.52
Total	46	100.00	46	100.00

Chi square 0.697, P value 0.403 (NS)

CHART 4: DISTRIBUTION ACCORDING TO MPG GRADING

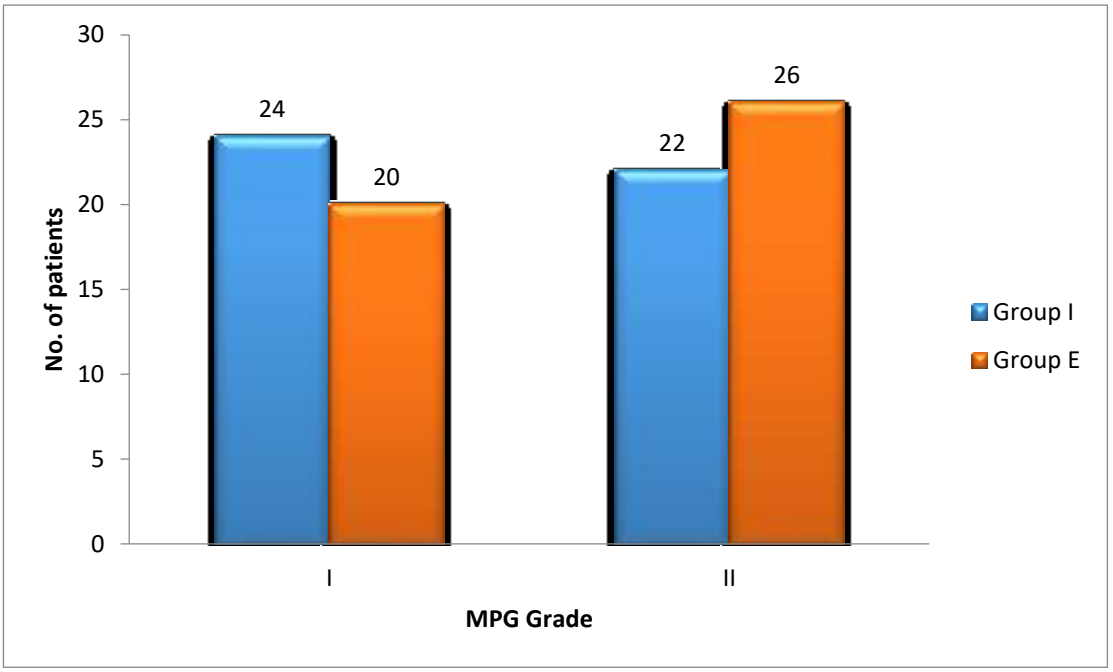


Table 4 demonstrates distribution according to MPG grading and data is analyzed using chi square test. In group I, 24 patients belonged to MPG Grade I and 22 patients in MPG Grade II, whereas in Group E, there were 20 patients in MPG Grade I and 26 patients in MPG Grade II. The difference in both the groups were not statistically significant as p value is 0.403.

TABLE 5. DISTRIBUTION ACCORDING TO ATTEMPTS MADE TO INSERT AIRWAY DEVICE

Ease of insertion of airway device no. of attempts	Group I		Group E	
	N	%	N	%
First	42	91.30	35	76.09
Second	4	8.70	11	23.91
Total	46	100.00	46	100.00

Chi square 3.903, P value 0.048 (S)

CHART 5. DISTRIBUTION ACCORDING TO ATTEMPTS MADE TO INSERT AIRWAY DEVICE

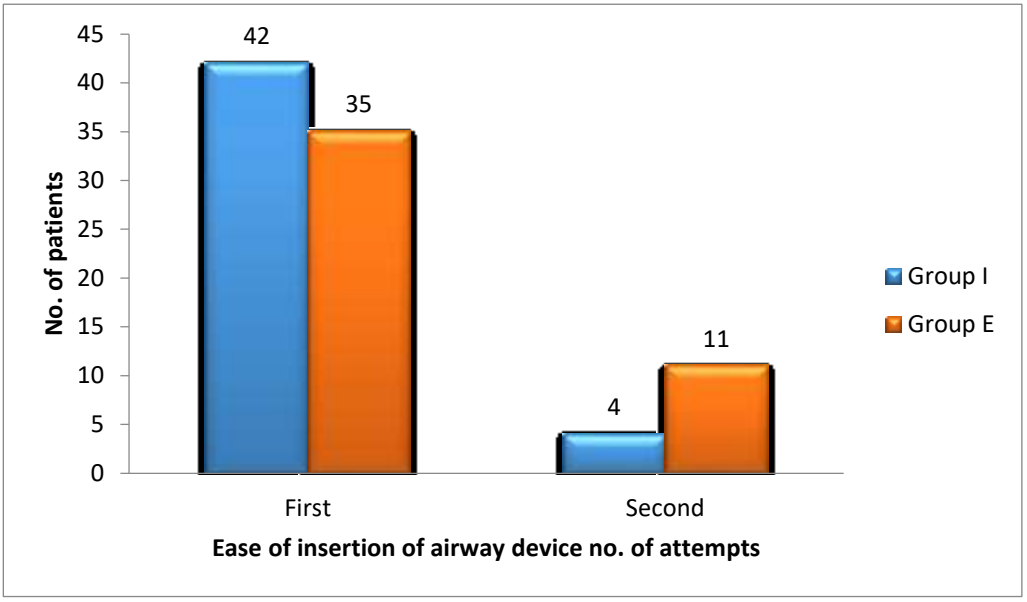


Table 5 demonstrates distribution according to no of attempts made to insert airway device and the data was analyzed using chi-square test. In group I in 91.3% of cases airway device placement was achieved in first attempt and in second attempt in 8.4 % of the cases. Where as in group E in 76.1% of cases airway device placement was achieved in the first attempt and in second attempt in 23.9 % of the cases .The difference in both the groups was statistically significant as p value is 0.048 .

TABLE 6. DISTRIBUTION ACCORDING TO ATTEMPTS MADE TO INSERT GASTRIC TUBE

Ease of insertion of gastric tube no. of attempts	Group I		Group E	
	N	%	N	%
First	44	95.65	32	69.57
Second	2	4.35	14	30.43
Total	46	100.00	46	100.00

Chi square 10.89, P value 0.001 (S)

CHART 6. DISTRIBUTION ACCORDING TO ATTEMPTS MADE TO INSERT GASTRIC TUBE

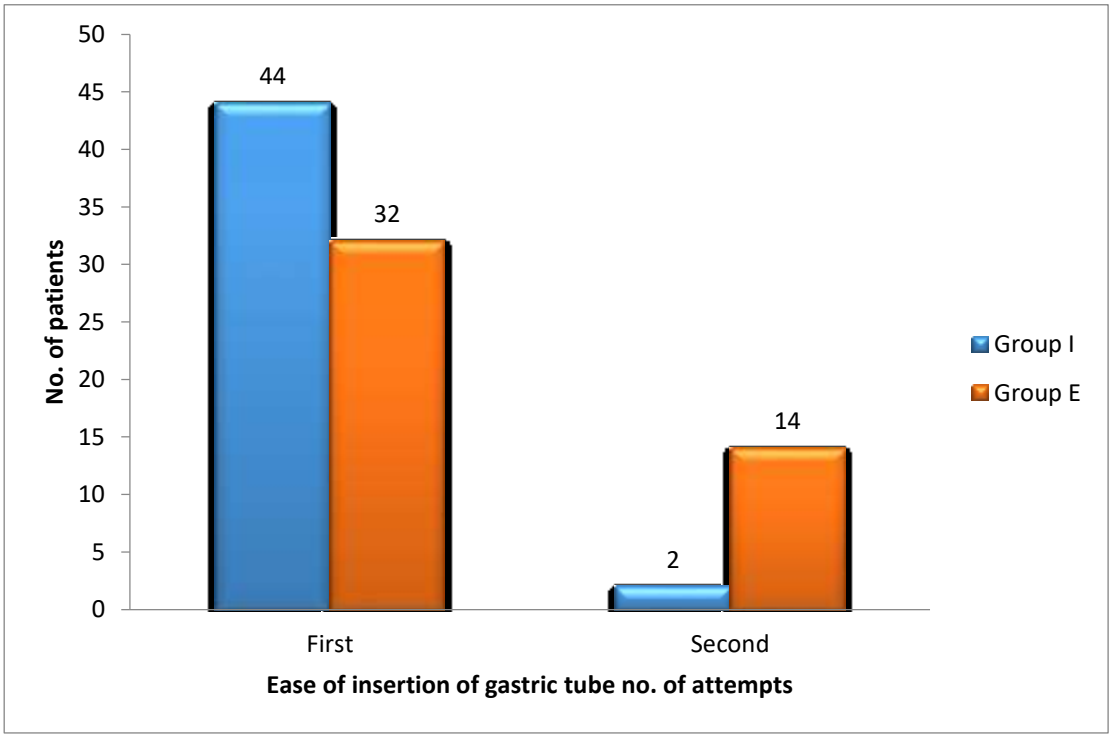


Table 6 demonstrates distribution according to no of attempts made to insert airway device and the data was analyzed using chi-square test. In group I in 95.65% of cases gastric tube placement was achieved in first attempt and in second attempt in 4.34% of the cases. Where as in group E in 69.6% of cases airway device placement was achieved in the first attempt and in second attempt in 30.4 % of the cases .The difference in both the groups was statistically significant as p value is 0.001 .

TABLE 7: DISTRIBUTION ACCORDING TO HEART RATE

Time	Heart Rate (bpm)		t value	p value
	Group I (Mean±SD)	Group E (Mean±SD)		
Baseline	84.67±10.12	81.61±10.7	1.412	0.161
Before airway placement	83.15±8.29	82.28±9.91	0.456	0.649
1 min. after airway placement	83.85±7.9	88.84±7.74	**3.680**	**0.0004**
3 min. after airway placement	83.15±6.03	87.65±5.96	**3.598**	**0.0005**
5 min. after airway placement	82.17±5.58	85.5±4.11	**3.256**	**0.001**
After pneumoperitoneum	87.74±8.43	88.13±4.69	0.275	0.783
Before extubation	82.5±6.95	80.09±4.9	1.925	0.057
After extubation	84.37±6.4	89.87±6.02	**4.247**	**<0.0001**

Unpaired t test

CHART 7: DISTRIBUTION ACCORDING TO HEART RATE

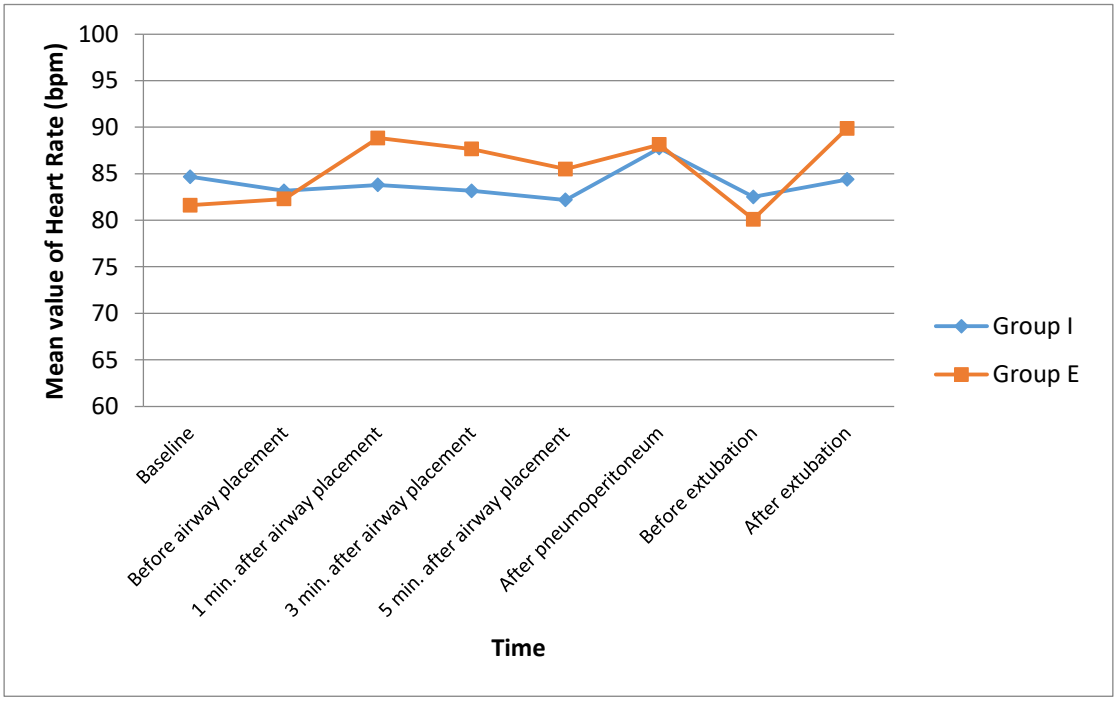


Table 7 is showing mean HR of both the groups at various time intervals in before and after placement of airway device and unpaired t test is used for data analysis. It was found that mean basal HR in group I were 84.67±10.12, 83.15±8.29 before airway device placement, 83.85±7.9 after 1 min, 83.15±6.03 after 3mins, 82.17±5.58 after 5mins of airway device placement, 87.74±8.43 after carboperitonium, 82.5±6.95 before extubation and 84.37±6.4 after extubation. In group E mean basal heart rate were 81.61±10.7, 82.28±9.91 before airway device placement, 88.84±7.74 after 1 minute, 87.65±5.96 after 3 minutes, 85.5±4.11 after 5 minutes of airway device placement, 88.13±4.69 after carboperitonium ,80.09±4.9 before extubation and 89.87±6.02 after extubation. So, the difference in mean HR of two groups was statistically significant at 1minute, 3minutes, 5minutes after placement of airway device and after extubation (ie. removal of the device) where p value was <0.05 i.e., 0.0004, 0.0005, 0.001 and <0.0001 respectively and it was statistically not significant at basal reading, before airway device placement, after carboperitonium, before extubation .($p>0.05$).

TABLE 8: DISTRIBUTION ACCORDING TO SYSTOLIC BLOOD PRESSURE (SBP)

Time	SBP (mmHg)		t value	p value
	Group I (Mean±SD)	Group E (Mean±SD)		
Baseline	120.74±9.62	121.87±9.44	0.568	0.57
Before airway placement	118.32±8.47	120.73±7.37	1.457	0.148
1 min. after airway placement	122.24±7.16	145.74±6.47	**16.51**	**<0.0001**
3 min. after airway placement	120.5±6.09	141±5.19	**17.38**	**<0.0001**
5 min. after airway placement	121.54±4.92	133.46±4.26	**12.41**	**<0.0001**
After pneumoperitoneum	128.26±6.10	129.30±3.92	0.975	0.331
Before extubation	123.91±5.89	122.43±5.01	1.298	0.198
After extubation	123.24±5.27	140.76±5.52	**15.56**	**<0.0001**

Unpaired t test

CHART 8: DISTRIBUTION ACCORDING TO SYSTOLIC BLOOD PRESSURE (SBP)

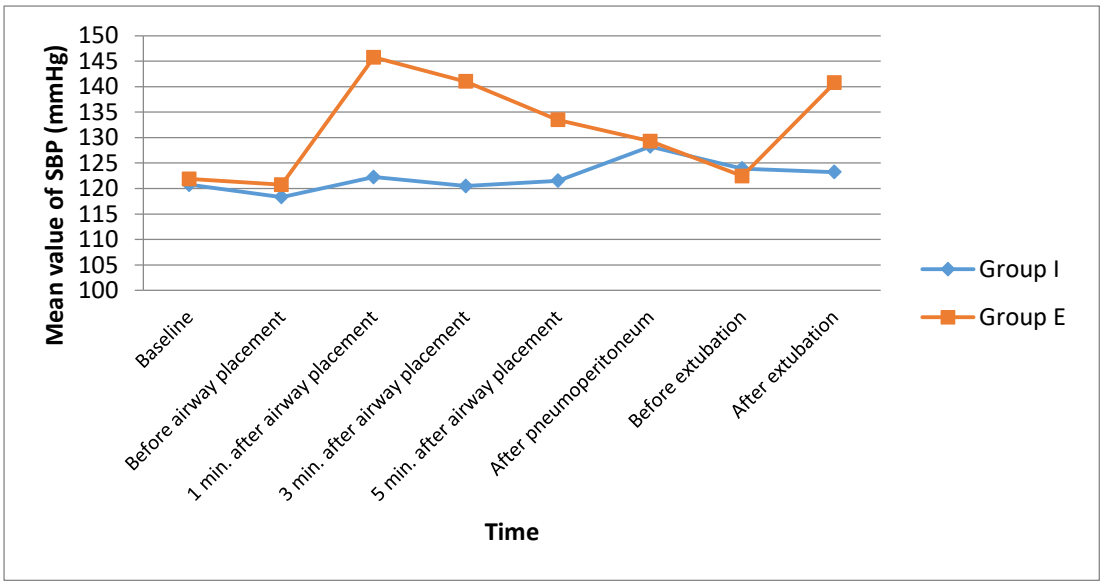


Table 8 is showing mean SBP of both the groups at various time intervals in before and after placement of airway device and unpaired t test is used for data analysis. It was found that mean basal SBP in group I were 120.74±9.62, 118.32±8.47 before airway device placement, 122.24±7.16 after 1 min, 120.5±6.09 after 3mins, 121.54±4.92 after 5mins of airway device placement , 128.26±6.10 after carboperitonium , 123.91±5.89 before extubation and 123.24±5.27 after extubation. In group E mean basal SBP were 121.87±9.44, 120.73±7.37 before airway device placement, 145.74±6.47 after 1 minute, 141±5.19 after 3 minutes, 133.46±4.26 after 5 minutes of airway device placement, 129.30±3.92 after carboperitonium ,122.43±5.01 before extubation and 140.76±5.52 after extubation . So, the difference in mean SBP of two groups was statistically significant at 1minute, 3minutes, 5minutes after placement of airway device and after extubation (i.e. removal of the device) where p value was <0.05 i.e <0.0010, <0.0001,< 0.0001 and <0.0001 respectively and it was statistically not significant at basal reading , before airway device placement, after carboperitonium, before extubation .($p>0.05$).

TABLE 9: DISTRIBUTION ACCORDING TO DIASTOLIC BLOOD PRESSURE (DBP)

Time	DBP (mmHg)		t value	p value
	Group I (Mean±SD)	Group E (Mean±SD)		
Baseline	78.8±6.38	79.28±6.74	0.349	0.727
Before airway placement	73.09±5.41	74.26±4.61	1.12	0.265
1 min. after airway placement	75.89±5.08	89.96±7.24	**10.77**	**<0.0001**
3 min. after airway placement	74.37±4.7	82.65±6.1	**7.294**	**<0.0001**
5 min. after airway placement	75.13±3.98	79.2±4.67	**4.491**	**<0.0001**
After pneumoperitoneum	77.26±4.83	78.13±4.09	0.931	0.354
Before extubation	74.02±4.26	75.61±4.63	1.711	0.09
After extubation	75±4.35	86.96±5.69	**11.32**	**<0.0001**

Unpaired t test

CHART 9: DISTRIBUTION ACCORDING TO DIASTOLIC BLOOD PRESSURE (DBP)

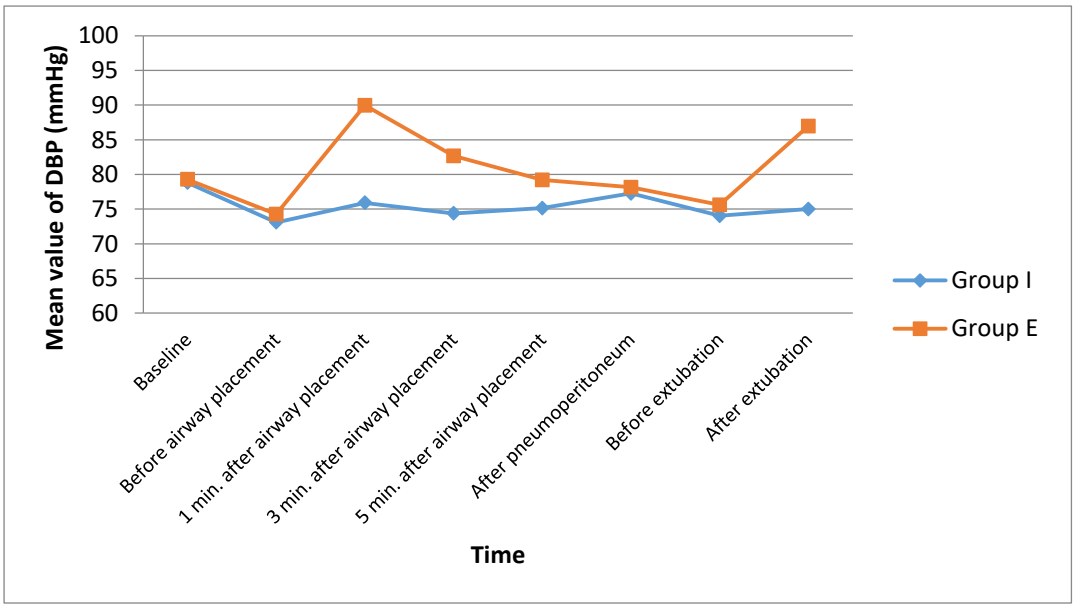


Table 9 is showing mean DBP of both the groups at various time intervals in before and after placement of airway device and unpaired t test is used for data analysis. It was found that mean basal DBP in group I were 78.8±6.38 , 75.89±5.08 before airway device placement ,75.89±5.08 after 1 min , 74.37±4.7 after 3mins , 75.13±3.98 after 5mins of airway device placement , 77.26±4.83 after carboperitonium , 74.02±4.26 before extubation and 75±4.35 after extubation. In group E mean basal DBP were 79.28±6.74 , 74.26±4.61 before airway device placement , 89.96±7.24 after 1 minute , 82.65±6.1 after 3 minutes , 79.2±4.67 after 5 minutes of airway device placement , 78.13±4.09 after carboperitonium ,75.61±4.63 before extubation and 86.96±5.69 after extubation . So the difference in mean DBP of two groups was statistically significant at 1minute, 3minutes, 5minutes after placement of airway device and after extubation (ie. removal of the device) where p value was <0.05 i.e <0.0001, <0.0001,< 0.0001 and <0.0001 respectively and it was statistically not significant at basal reading , before airway device placement, after carboperitonium, before extubation ($p>0.05$).

TABLE 10 : DISTRIBUTION ACCORDING TO MEAN BLOOD PRESSURE (MBP)

Time	MBP (mmHg)		t value	p value
	Group I (Mean±SD)	Group E (Mean±SD)		
Baseline	92.76±5.85	92.96±6.63	0.15	0.881
Before airway placement	88.17±5.17	89.75±4.57	1.546	0.125
1 min. after airway placement	91.39±4.75	108.57±6.25	**14.84**	**<0.0001**
3 min. after airway placement	89.96±4.13	102.09±4.88	**12.88**	**<0.0001**
5 min. after airway placement	90.46±3.24	97.33±3.73	**9.434**	**<0.0001**
After pneumoperitoneum	94.26±3.48	95.19±2.81	1.523	0.131
Before extubation	90.52±3.74	91.17±3.2	0.898	0.371
After extubation	91.07±3.36	104.91±4.9	**15.81**	**<0.0001**

Unpaired t test

TABLE 10 : DISTRIBUTION ACCORDING TO MEAN BLOOD PRESSURE (MBP)

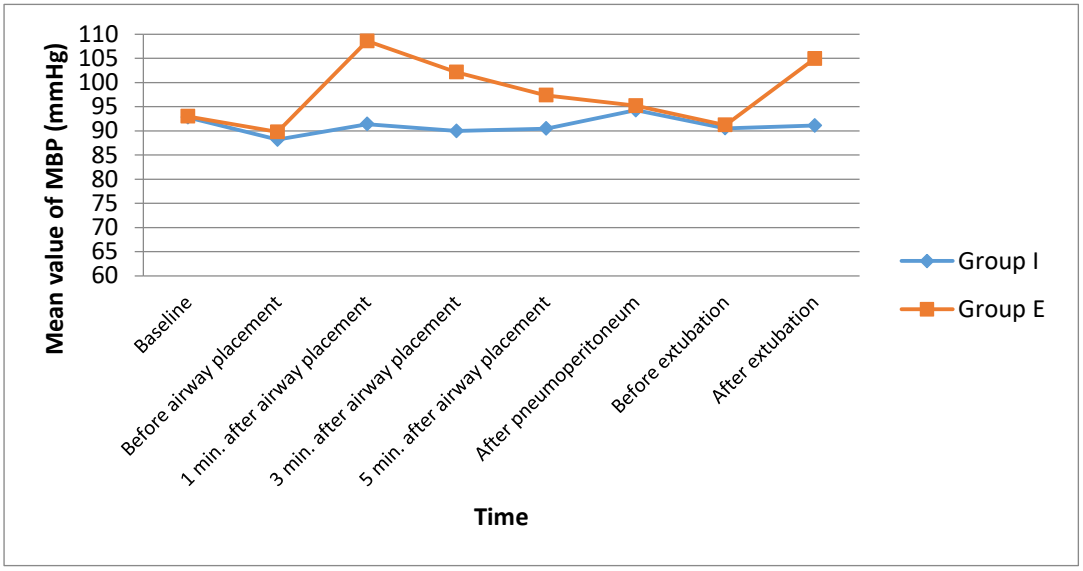


Table 10 is showing mean MBP of both the groups at various time intervals in before and after placement of airway device and unpaired t test is used for data analysis. It was found that mean basal MBP in group I were 92.76±5.85, 88.17±5.17 before airway device placement, 91.39±4.75 after 1 min, 89.96±4.13 after 3mins, 90.46±3.24 after 5mins of airway device placement, 94.26±3.48 after carboperitonium, 90.52±3.74 before extubation and 91.07±3.36 after extubation. In group E mean basal MBP were 92.96±6.63, 89.75±4.57 before airway device placement, 108.57±6.25 after 1 minute ,102.09±4.88 after 3 minutes, 97.33±3.73 after 5 minutes of airway device placement, 95.19±2.81 after carboperitonium, 91.17±3.2before extubation and 104.91±4.9 after extubation. So the difference in mean DBP of two groups was statistically significant at 1minute, 3minutes, 5minutes after placement of airway device and after extubation (i.e. removal of the device) where p value was <0.05 i.e <0.0001, <0.0001,< 0.0001 and <0.0001 respectively and it was statistically not significant at basal reading , before airway device placement, after carboperitonium, before extubation ($p>0.05$) .

TABLE 11: DISTRIBUTION ACCORDING TO SPO2

Time	SPO2 (%)		t value	p value
	Group I (Mean±SD)	Group E (Mean±SD)		
Baseline	98.67±0.6	98.59±0.72	0.361	0.529
Before airway placement	99.22±0.47	99.11±0.38	1.226	0.223
1 min. after airway placement	99.13±0.45	99.13±0.34	0.000	1.000
3 min. after airway placement	99.07±0.39	99.15±0.42	1.031	0.305
5 min. after airway placement	99.09±0.41	99.15±0.36	0.805	0.423
After pneumoperitoneum	99.07±0.39	99.13±0.5	0.699	0.486
Before extubation	99.07±0.39	99.11±0.57	0.429	0.668
After extubation	99.07±0.39	99.13±0.45	0.741	0.460

Unpaired t test

CHART 11: DISTRIBUTION ACCORDING TO SPO2

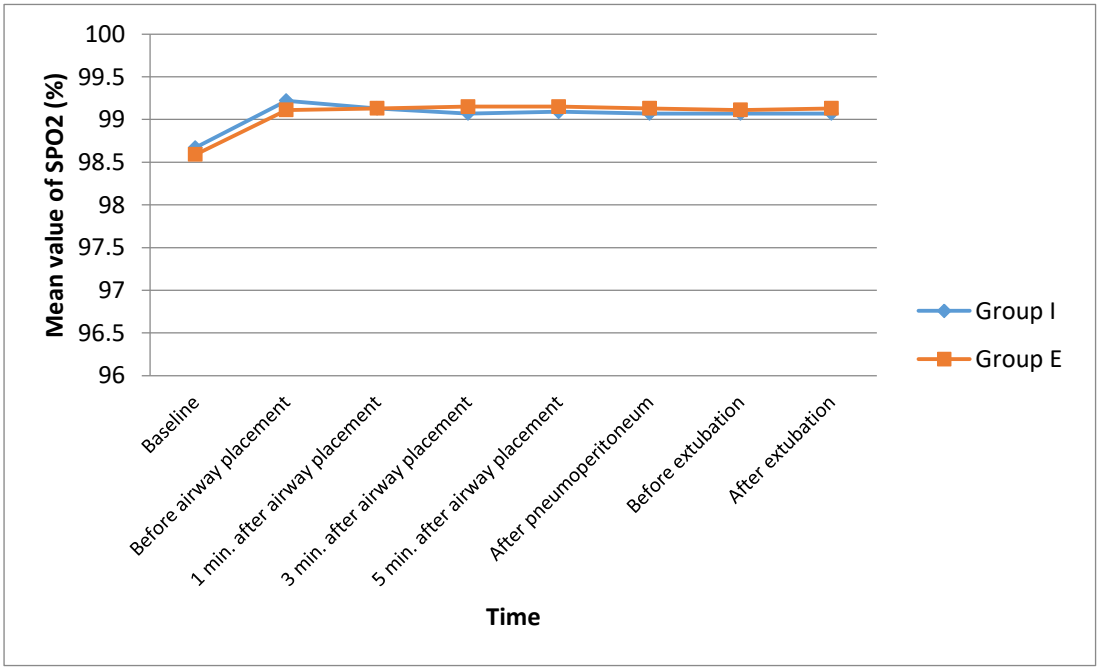


Table 11 is showing mean SPO2 of both the groups at various time intervals in before and after placement of airway device and unpaired t test is used for data analysis. It was found that mean basal SPO2 in group I were 98.67±0.6, 99.22±0.47 before airway device placement, 99.13±0.45 after 1 min, 99.07±0.39 after 3mins, 99.09±0.41 after 5mins of airway device placement, 99.07±0.39 after carboperitonium, 99.07±0.39 before extubation and 99.07±0.39 after extubation. In group E mean basal SPO2 were 98.59±0.72, 99.11±0.38 before airway device placement, 99.13±0.34 after 1 minute, 99.15±0.42 after 3 minutes, 99.15±0.36 after 5 minutes of airway device placement, 99.13±0.5 after carboperitonium, 99.11±0.57 before extubation and 99.13±0.45 after extubation. So, the difference in mean SPO_2 of two groups was not statistically significant at all-time intervals ($p>0.05$).

TABLE 12: DISTRIBUTION ACCORDING TO PEAK PRESSURES AND ETCO2

Variables		Group I (Mean±SD)	Group E (Mean±SD)	t value	p value
Peak airway pressure	Before carboperitonium	13.60±1.99	13.69±2.10	0.203	0.839
	After carboperitonium	17.58±2.01	17.78±1.88	0.48	0.631
E2CO2	Before carboperitonium	32.30±1.42	32.86±1.54	1.823	0.071
	After carboperitonium	37.71±1.37	37.19±1.43	1.628	0.106

Unpaired t test

CHART 12 (A): DISTRIBUTION ACCORDING TO PEAK PRESSURES

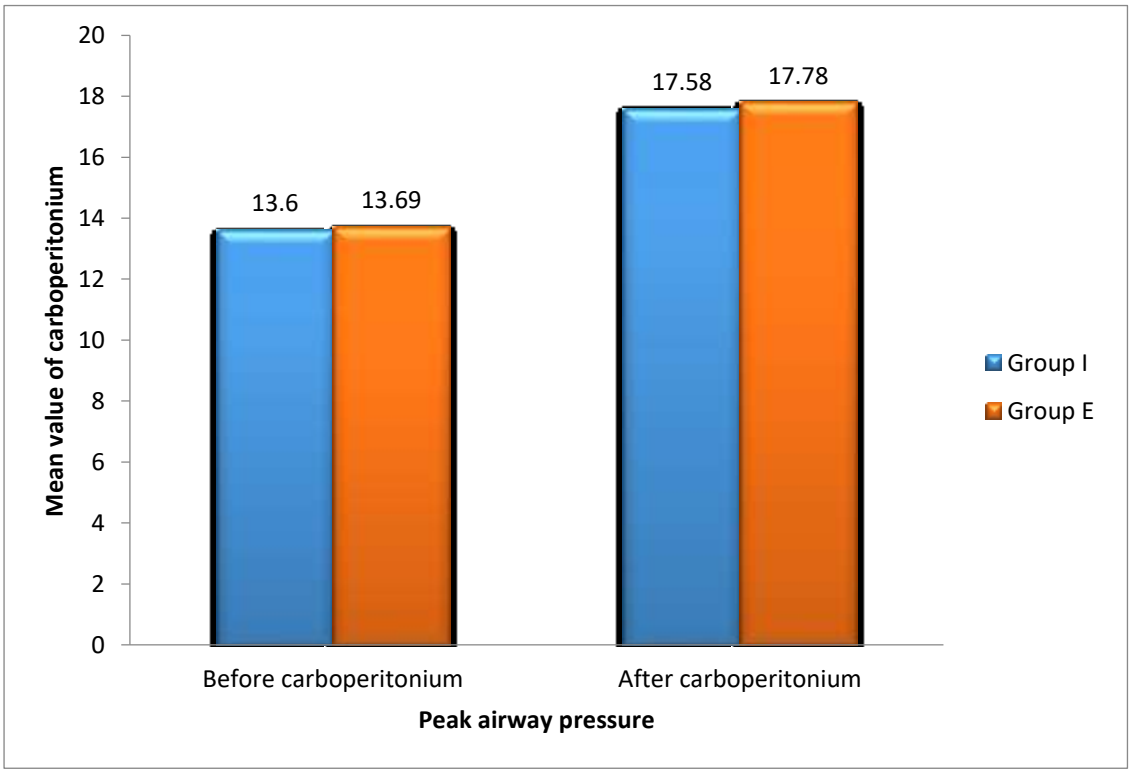


CHART 12 (B) : DISTRIBUTION ACCORDING TO ETCO2

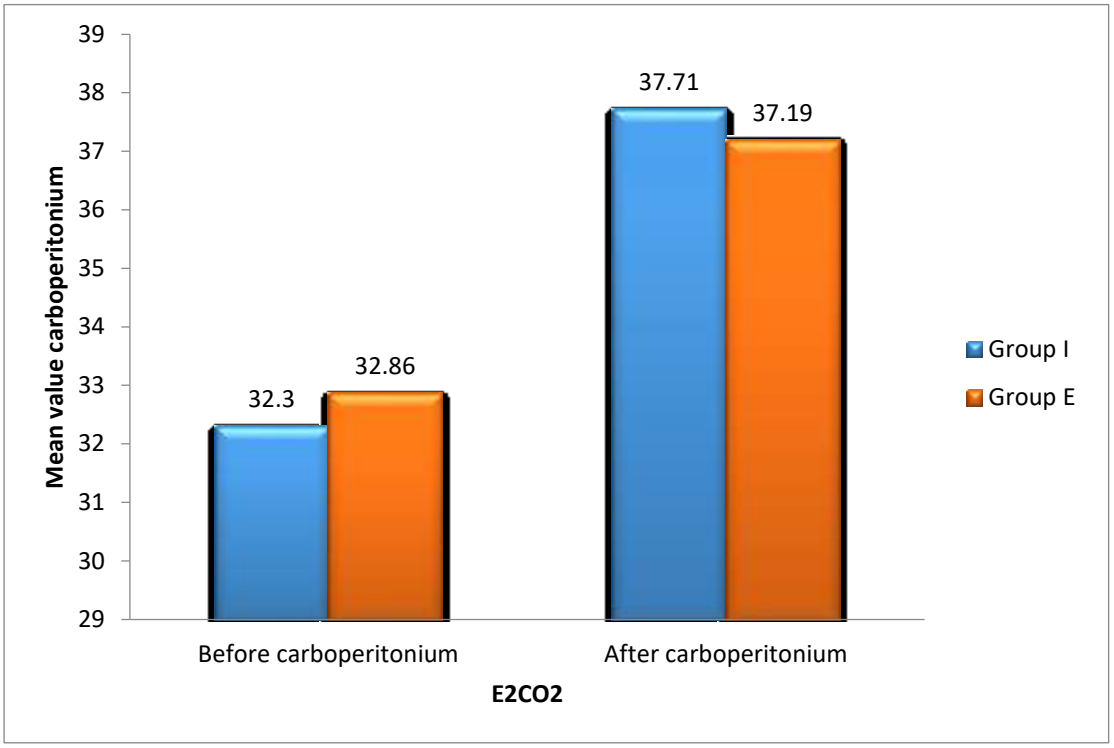


Table 12 is showing mean peak airway pressures and ETCO2 changes in both groups before and after carboperitonium and unpaired t test is used for data analysis. It was found that mean peak pressures in group I before carboperitonium were 13.60±1.99 and 17.58±2.01 after carboperitonium and ETCO2 in group I before carboperitonium were 32.30±1.42 and 37.71±1.37 after carboperitonium. In group E mean peak airway pressures before carboperitonium were 13.69±2.10 and 17.78±1.88 after caboperitonium and ETCO2 in group E before carboperitonium were 32.86±1.54 and 37.19±1.43 after carboperitonium. So the difference in mean peak airway pressures and mean ETCO2 of two groups was not statistically significant at both intervals ($p>0.05$).

TABLE 13: DISTRIBUTION ACCORDING TO POST OPERATIVE COMPLICATIONS

Post op complications	Group I		Group E		P value
	N	%	N	%	
Blood on device	0	0.00	3	6.52	0.241
Sore throat	3	6.52	5	10.87	0.713
Hoarseness of voice	1	2.17	3	6.52	0.616
Nausea & vomiting between 0 and 24 hrs	2	4.35	4	8.70	0.676

Fisher exact test

CHART 13: DISTRIBUTION ACCORDING TO POST OPERATIVE COMPLICATIONS

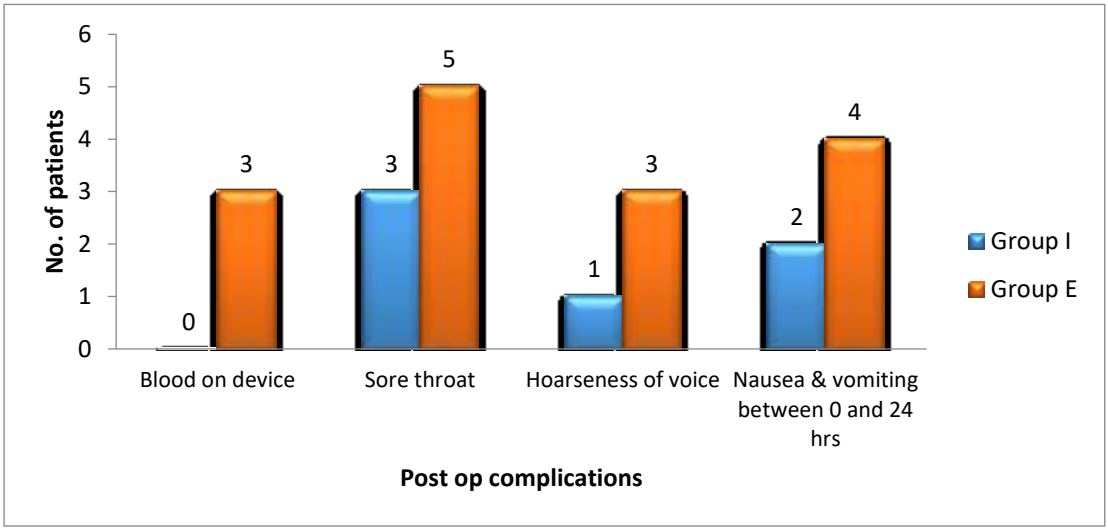


Table 13 is showing distribution according to post operative complications in both groups and fisher exact test is used for data analysis. It was found that the incidence of visible blood after removal of airway device in group E was 6.25% (3/46 patients). there was no incidence of visible blood in group I after removal of airway device. 10 .87% (5/46) patients in group E developed sore throat and other 6.25% (2/46) patients developed hoarseness of voice post operatively. In group I incidence of sore throat and hoarseness of voice were6.52% (3/46 patients) and 2.17 % (1/46 patients) respectively. Incidence of post operative nausea and vomiting in group I was 4.35 % and group E was 8.70 % . no significant post operative complications were observed as both groups as p value >0.05.

DISCUSSION

Supraglotting airway devices have several proven advantages over tracheal tubes. The few advantages with the use of SDAs are easy insertion(56) fewer hemodynamic fluctuations during an aesthesia (57)decreased incidence of sore throat (58) and others. Therefore, a rising tendency is emerging to replace regulated breathing with a SAD in patients with little aspiration risk.

Therefore, the current study was designed as prospective interventional comparative study among the two airway devices (I-gel, and tracheal tube) used during general anaesthesia with positive pressure ventilation for laparoscopic cholecystectomy. This study revealed that I-gel produces the least hemodynamic perturbations, ease of insertion of airway device as well as gastric tube among the two devices with acceptable oxygenation and ventilation.

In our study, we found that I-gel was inserted with more ease in first attempt in42 (91.30%) patients as compared to endotracheal tube where only 35 (76.09%) patients were intubated in 1st attempt (statistically significant, p value -0.048). Second attempt was required in 4(8.70%) and 11(23.91.7%) patients respectively in group I, E. None of the patient required third attempt , failed device insertion in any groups. Thus insertion of I-gel was significantly easier as compared to endotracheal tube (p -0.048) . Our finding is consistent with a study by Teoh et al (51) and Theiler et al(59,60) that showed a success rate of 96 % with I- gel at first attempt. Najeeb et al (60) stated that I-gel was easier to insert with higher success rate in 1st attempt (92.5%) than endotracheal tube (82.5%) .We believe that easier insertion of I-gel was because of the design which was inspired by physiology of the perilaryngeal framework itself. The shape, softness and contour accurately mirror image the perilaryngeal anatomy to create the perfect seal and no cuff inflation is required.

In our study we observed that ryle's (gastric) tube was inserted in 44 (95.65%) patients in 1st attempt of Group I and 32 (69.57%) patients of Group E (statistically significant, p value-0.001). Previous studies conducted by Singh I. et al(61) Saraswat N. et al (62) found that the ease of insertion of ryle's tube was 100% with I-gel and success rate of NG tube insertion in 1st attempt was 66.67% via nasal route in intubated patients respectively . These studies show that the SAD's (I-gel) have

significantly higher success rate for gastric tube insertion than conventional placement via nasal route. This can be explained by the fact that the SAD's have a separate port for gastric tube insertion through which gastric tube can be easily inserted without coiling in airway tract.

In our study we observed there was no significant difference in the HR (p value - 0.649), SBP (p value -0.148), DPB (p value-0.265), MAP (p value-0.125) before insertion of airway device between the two groups. Following insertion of airway device there was significant rise in HR (p value - 0.0004), SBP (p value <0.0001), DBP (p value<0.0001) and MAP (p value <0.0001) at 1 min after intubation. At 3 and 5 minutes after insertion of airway device there was significant rise in HR (p values - 0.0005, 0.001), SBP (p values <0.0001), DPB(p values <0.0001) , MAP (p values <0.0001) in Group-E patients when compared to Group-I patients. However, after 5 min of intubation till the removal of airway device (before extubation) the changes in hemodynamic parameters were comparable in both groups. Following removal of airway device (i.e. after extubation) there was significant rise in HR (p value <0.0001), SBP (p value <0.0001) , DBP (p value <0.001) and MAP (p value <0.001) in Group-E patients when compared to Group-I patients.

Our finding is consistent with a study by Badheka, et al(40) that showed, following insertion of airway device there was significant rise in PR (just after intubation, 3 min after intubation and MAP (just after intubation, 3 min after intubation, 5 min after intubation in patients who were intubated with the help of an endotracheal tube when compared to patients with gel insertion. Ravindra Kumar Gehlot et al(37) reported Hemodynamic changes (Heart rate & MAP) were significantly higher in endotracheal group than the I-gel group immediately after intubation and persisted for 3 minutes thereafter and immediately after extubation. Maharjan SK et al(46) reported significant difference in HR, SBP, DBP and MAP among endotracheal tube and I-gel after one minute of use of airway device and after removal of the device.

The hemodynamic findings in our study can be is attributed to the hemodynamic stress response due to manipulation of pharynx, larynx and trachea during laryngoscopy and intubation because of the surge of catecholamine and cortisol despite different minimizing measures.(63,64)The I-gel being supraglottic devices do not require laryngoscopy and probably do not evoke a significant sympathetic

response. Attenuation of this response may be due to diminished catecholamine release. Another important aspect is that probably there is minimal stress response and hemodynamic perturbation with I-gel use which, being minimal, is blunted by use of anaesthetics during general anaesthesia.

During the study period, airway pressure was well maintained during carboperitoneum with Endotracheal tube and I-gel as well. The mean and standard deviation of maximum airway pressures recorded after carboperitoneum were 17.58± 2.01 and 17.78±1.88 cmH2 O for I-gel and tracheal tube respectively, which were statistically not significant (p value 0.631). Oxygenation and ventilation were well maintained with both airway devices. Oxygen saturation was maintained between 98 to 100 per cent and end tidal CO2 was maintained between 32 to 37 mmHg during the intraoperative period. The following findings are consistent with Maharjan SK et al (46)and Uppal V et al(53)who reported no significant difference in maximum airway pressures and end tidal CO2 when endotracheal tube is compared with I- gel for controlled ventilation in patients undergoing laparoscopic cholecystectomies .

In our study, no significant post operative complications. We did not observe any incidence of regurgitation. The incidence of visible blood on Endotracheal tube after removal in our study was 6.25% (3/46 patients). there was no incidence of visible blood with the use of I-gel after removal. We observed 10 .87% (5/46) patients with endotracheal tube insertion developed sore throat and other 6.25% (2/46) patients developed hoarseness of voice post operatively. When compared to I-gel group incidence of sore throat and hoarseness of voice were6.52% (3/46 patients) and 2.17 % (1/46 patients) respectively. incidence of post operative nausea and vomiting in I- gel group was 4.35 % and endotracheal group 8.70 % which was statistically not significant.

SUMMARY

The most common anesthetic technique in laparoscopic cholecystectomy is general anesthesia with controlled ventilation which is often achieved with the help of an endotracheal tube (ETT). However, during the surgery, high intra-abdominal pressures due to carbon dioxide insufflation increases the risk of passive gastroesophageal regurgitation and carbon dioxide retention. For these reasons, cuffed ETT is the most preferred technique when considered in terms of safety. (65)
Ever since the development of Supraglottic airway device (SAD) by Dr Archie Brain, SADs have been used as a convenient alternative to ETT, with easy and atraumatic insertion, as well as minimal somatic and autonomic responses in many clinical conditions. However, SADs have some disadvantages, like limited protection of the airway from gastric contents. (66) The second generation SADs have overcome this issue. One of these is the I-Gel which is made of medical grade thermoplastic elastomer (styrene ethylene butadiene styrene) and does not require an inflating cuff. Its design provides a peri laryngeal seal without cuff inflation. In addition, it is easily and rapidly placed, with a reduced risk of pharyngeal tissue compression. Moreover, it has a gastric drainage tube, and it allows the insertion of a gastric tube and aspiration of the gastric contents and air. The I-gel provides lower respiratory complications and can seal higher oropharyngeal leak pressures than the earlier SADs. Various studies reported that I-gel is found equally effective device to provide positive pressure ventilation in laparoscopic surgeries.

The randomized comparative study titled " A Randomized Comparative Study Of I-Gel and Endotracheal Tube In Patients Undergoing Elective Laparoscopic Cholecystectomy " was conducted in the department of Anaesthesiology in Santosh Medical College & Hospital, on 92 patients aged between 18 to 60 years, either sex, ASA physical status I & II, undergoing elective laparoscopic cholecystectomy under general anaesthesia, after getting approval from institutional ethics committee and obtaining written informed consent from each of the patient.

92 patients were randomly divided into two groups:

Group I – Patients receiving I -gel as airway device (n = 46)
Group E – Patients receiving endotracheal tube as airway device (n =46)

The efficacy in terms of ease of airway device insertion, ease of gastric tube insertion, haemodynamics (systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, SPO2) at different intervals throughout the surgery and ETCO2 and peak pressure variations after carboperitonium and any post operative complications for a period of 24 hrs. after the surgery were assessed.

The data collected during the study was compiled using a Microsoft Excel spread sheet and analyzed statistically using the statistical package for the MedCalc statistical Software version 20.115 for window editions.

There was no statistically significant difference found among the groups in terms of the demographic variables. Statistically significant difference was found in terms of ease of insertion of airway device and gastric tube placement in which I-gel group was found to be superior to endotracheal tube. There was a significant increase in the Hemodynamic parameters (HR, SBP, DBP, MAP) in group E after insertion of airway device, at 1 min ,3min ,5min after insertion of airway device and just after removal of the airway device. there was no statically significance found among the group in ETCO2 and peak pressure changes after carboperitonium. Oxygenation and ventilation were well maintained with both airway devices. Oxygen saturation was maintained between 98 to 100 per cent and end tidal CO2 was maintained between 32 to 37 mmHg during the intraoperative period. In our study, no significant post operative complications were observed.

Hence, it was observed from this study that I-gel is an equally effective airway device as endotracheal tube. The supraglottic air way device I-gel is easy to insert and maintains hemodynamic parameters will less perturbations and lesser post operative complications as compared to endotracheal tube in laparoscopic cholecystectomy surgery under general anaesthesia with controlled ventilation.

CONCLUSSION

Through this study We concluded that I-gel requires less time for insertion with minimal hemodynamic changes when compared to endotracheal tube. I-gel also provides adequate positive-pressure ventilation, comparable with ETT. In addition, the gastric channel in I-gel provides protection against aspiration and ease of insertion of gastric tube. Hence, I-gel can be a safe and suitable alternative to endotracheal tube for laparoscopic cholecystectomy surgery under general anaesthesia with controlled ventilation.

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ANNEXURE 1

PROFORMA

1. GENERAL INFORMATION

Name	
Age (in years)/ Sex	
Occupation	
Address	
Diagnosis	
Operation proposed	
MRD No.	
Surgery Unit	
Date	

2. GENERAL EXAMINATION

General Condition	
Any positive history	
Heart Rate(beats per minute)	
Blood Pressure(in mm of Hg)	
Temperature (in degree Fahrenheit)	
Spo2 (in %)	
Mouth Opening	
MPG grade	
Neck movement	
Oral examination	
ASA Grade	

3. SYSTEMIC EXAMINATION:

System	Findings
Respiratory system	
Cardiovascular system	
Central nervous system	
Per abdomen(G.I system)	

4. ANY SYSTEMIC DISEASE:

5. INVESTIGATIONS:

6. DEMOGRAPHIC PARAMETERS:

Parameters	
Age	
Weight (BMI)	
Height	
Duration of surgery	

7. GROUP ALLOCATON:

GROUP I:	
GROUP E:	

8. INSERTION OF AIRWAY DEVICE:

	No. of attempts
GROUP I:	
GROUP E:	

9. EASE OF INSERTION OF GASTRIC TUBE:

No. of gastric tube insertion attempts	GROUP I	GROUP E

10. PEAK AIRWAY PRESSURE CHANGES:

	GROUP I	GROUP E
Before pneumoperitoneum		
After pneumoperitoneum		

11. POST OPERATIVE COMPLICATIONS:

	GROUP I	**GROUP E**
BLOOD ON DEVICE	**YES /NO**	**YES /NO**
SORE THROAT	**YES /NO**	**YES /NO**
HORSENESS OF VOICE	**YES /NO**	**YES /NO**
NAUSEA AND VOMITING BETWEEN 0AND 24 HRS	**YES /NO**	**YES /NO**

12 .HEMODYNAMIC CHANGES:

Time	Group I					Group E				
Baseline	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2
Before airway placement										
1 min. after airway placement										
3 min. after airway placement										
5 min. after airway placement										
After pneumoperitoneum										
Before extubation										
After extubation										

ANNEXURE 2

DEPARTMENT OF ANAESTHESIA SANTOSH MEDICAL COLLEGE & HOSPITAL GHAZIABAD, U.P

I am being requested to take part in a study entitled.

" A Randomized Comparative Study Of I-Gel and Endotracheal Tube In Patients Undergoing Elective Laparoscopic Cholecystectomy "

VOLUNTARY PARTICIPATION

My participation in the study is entirely voluntary and I am free to with draw from the study as and when I feel

Name ----------

Signature ----------

INFORMED CONSENT FORM

I _____ son/daughter/wife of _____ resident of_____ give my full, free and voluntary consent to be included as a subject in the study entitled " A Randomized Comparative Study Of I-Gel and Endotracheal Tube In Patients Undergoing Elective Laparoscopic Cholecystectomy " I have been explained, in my own language, and to my full satisfaction, the aim and nature of the study and risks and benefits. I have also been explained that my confidentiality will be maintained and all the investigations/ interventions will be carried out only after my consent is obtained. I am aware of my right to opt out of the study at any point without giving any reason, and without penalty or loss of routine care benefits.

Patient's/ Patient's relative's signature Doctor's Signature:

Or thumb impression.

Name: Date:

We have witnessed that the patient signed the above form in the presence of his free will after fully understanding its content.

Signature of Witness

Name:

Signature of Investigator

Name:

ANNEXURE 3

संतोषमेडिकलकॉलेजएवंअस्पताल (गाजियाबाद)

सूचितसहमति

मैं_____बेटा_____निवासी_____

_____ घोषणा करता हूं कि मैं डॉ._____, ने मेरी भाषा में अपने अध्ययन, अध्ययन के उद्देश्य के बारे मे, और अध्ययन के दौरान अपनाई जानेवाली विभिन्न प्रयोगशाला जांच के बारे में सूचित कर दिया है। मुझे अध्ययन की अवधि और उस के दौरान अपनाए जानेवाले निर्देश भी मेरी भाषा मे समझा दिए गए हैं| मैं उपरोक्त अध्ययन में बिना किसी दबाव के दाखिला ले रहा हूं और पूर्ण सहमति दे रहा हूं| सन्तोषअस्पताल, गाजियाबाद में अपने आगे के उपचार पर बिना प्रतिकूल प्रभाव डाले इस अध्ययन से और प्रयोगशाला जांच की प्रकृति से मैं जब चाहूँ बाहर जाने के अपने अधिकार को सुरक्षित रख रहा हूं I

रोगी / रोगी के रिश्तेदार के हस्ताक्षर डॉक्टर के हस्ताक्षर या अंगूठे का निशान

नाम

नांक:

मेरी उपस्थिति में मरीज ने पूरी तरह से डाकटर के बताए गए अध्ययन और निर्देशों को समझने के बाद अपनी स्वतंत्र इच्छा से ऊपरके फार्म पर हस्ताक्षर कि ए हैं

Signature of Investigator

ANNEXURE 4

LIST OF ABBREVIATIONS

1. LC- LAPAROSCOPIC CHOLECYSTECTOMY
2. EOI – EASE OF INSERTION
3. HOV – HOARSNESS OF VOICE
4. IPPV – INTERMITTENT POSTIVE PRESSURE VENTILATION
5. SAD – SUPRAGLOTTIC AIRWAY DEVICE
6. ALMA - AMBU LARYNGEAL MASK AIRWAY
7. LMA – LARYNGEAL MASK AIRWAY
8. PLMA – PROCEAL LARYNGEAL MASK AIRWAY
9. ETT – ENDOTRACHEAL TUBE
10. SD – STANDARD DEVIATION
11. LA – LOCAL ANESTHETIC
12. NSAID- NON STEROIDAL ANTI INFLAMMATORY DRUGS
13. CO2 – CARBON DIOXIDE
14. I M- INTRA MUSCULAR
15. I V – INTRA VENOUS
16. CNS – CENTRAL NERVOUS SYSTEM
17. HR- HEART RATE
18. SBP – SYSTOLIC BLOOD PRESSURE
19. DBP – DIASTOLIC BLOOD PRESSURE
20. MAP – MEAN ARTERIAL PRESSURE
21. DOA- DURATION OF ANALGESIA
22. SPO2 – OXYGEN SATURATION
23. ETCO2 - END TIDAL CARBON DIOXIDE
24. DOS – DURATION OF SURGERY
25. ASA – AMERICAN SOCIETY OF ANAESTHESIOLOGY

ANNEXURE 5

ETHICAL COMMITTEE CLEARANCE

SANTOSH
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

F. No. SU/2021/1830[42] Dated: 17.07.2021

Subject: Grant of Ethical Clearance for Thesis Protocol Topic **"A RANDOMISED COMPARATIVE STUDY OF I-GEL AND ENDOTRACHEAL TUBE IN PATIENTS UNDERGOING ELECTIVE LAPROSCOPIC CHOLECYSTECTOMY."**, submitted by **Dr. Akshay Bist,** MD/MS student of Batch 2020-2021, Department of **Anaesthesia**.

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled **"A RANDOMISED COMPARATIVE STUDY OF I-GEL AND ENDOTRACHEAL TUBE IN PATIENTS UNDERGOING ELECTIVE LAPROSCOPIC CHOLECYSTECTOMY."**, **Dr. Akshay Bist** is informed that the Thesis Protocol submitted by him/her was considered by the **Screening Committee** of the Santosh Medical College & Hospital in its meetings held on 19.03.2021, 22.03.2021, 24.03.2021, 25.03.2021, 26.03.2021, 27.03.2021 and 06.04.2021. The recommendations of the **Screening Committee** were considered in detail by the Institutional **Ethics Committee** in its meeting held on **12.07.2021** and the same was **approved** by the **Ethics Committee**.

He /She is informed accordingly for further necessary action.

[Dr. V. P. Gupta]
REGISTRAR

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, NCR (U.P.)

Dr. Akshay Bist
MD/MS student of batch 2020-2021
Department of Anaesthesia
Email: akshaybist199402@gmail.com

Copy to:

1. The Vice Chancellor
2. The Dean, SMC&H
3. The Dean – Research
4. The Dean – Academics
5. The Director - IQAC
6. Dr.Gaurav Dwivedi (Guide)
7. HOD of **Anaesthesia**

ANNEXURE 6

PLIAGARISM CERTIFICATE

Ouriginal

Document Information

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